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INSTITUTIONAL REVIEW BOARDS AND THE CONSTITUTION

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INTRODUCTION

Several participants in this symposium make a strong case that federal Institutional Review Board ("IRB") regulations stifle valuable scientific research.[1] But even if IRB regulations are perfectly dreadful social policy, it does not follow that they are unconstitutional. Both in this symposium and in a previous article,[2] however, Philip Hamburger makes a sustained argument that IRB regulations are indeed unconstitutional. Specifically, he argues that these regulations constitute a content-based prior restraint on speech in violation of the First Amendment. In Professor Hamburger's view, these constitutional problems exist even though federal IRB regulations are not directly imposed on research institutions by force of law but rather are adopted by these institutions as a condition on receiving federal research funds.

Contrary to Professor Hamburger, I do not believe that IRB regulations would constitute a facially unconstitutional infringement of free speech even if directly imposed on research institutions. That these regulations are adopted by research institutions as a condition of receipt of federal funding makes any facial attack on their constitutionality even less tenable. But this does not mean that IRBs are free of constitutional problems. Indeed, although IRB regulations are constitutional on their face and in most of their

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[1] The core IRB regulations are imposed as a condition of federal research funding by the so called "Common Rule," an identically worded set of regulations adopted by seventeen federal agencies. The Common Rule requires any institution receiving federal research funds to establish one or more IRBs, consisting of at least five members, at least one of whom is not affiliated with the institution. *See* 45 C.F.R. §§ 46.103(b)(2), 46.107(a)(d) (2005). Any researcher wishing to use human subjects on a project supported by federal funds must obtain prior approval from an IRB. 45 C.F.R. § 46.109 (2005). Requirements for IRB approval include that: (1) the risks to subjects are minimized; (2) risks to subjects are reasonable in relation to anticipated benefits; (3) selection of subjects is equitable; (4) informed consent will be sought and documented; and (5) there are adequate provisions for protection of the privacy of the subjects and maintenance of the confidentiality of the data. 45 C.F.R. § 46.111 (2005).

[2] Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271.

applications, certain applications pose difficult First Amendment questions. In addition, various applications of these regulations might implicate the constitutional right of thought and inquiry.

An obvious impediment to any claim that IRB regulations violate the right of free speech is that much scientific research involves primarily conduct and very little expression. This is particularly true of biomedical research, which involves such activities as organ transplants, blood draws, drug studies, and brain scans. Other types of research do, however, contain significant communicative elements. Social science research in particular typically involves the use of surveys, questionnaires or conversations to elicit information from subjects, as well as written and oral instructions to subjects as part of experiments. Because of this marked difference, I shall deal with biomedical and social science research separately.[3]

As Part I of the Article demonstrates, an insurmountable obstacle to any First Amendment challenge to the application of IRB regulations to ordinary biomedical research is that this type of research is not "speech" within the meaning of the First Amendment. As such, this activity would not be entitled to any First Amendment protection unless it were deemed either "expressive conduct" or an "essential precondition" to speech. Biomedical research does not qualify as expressive conduct because, unlike flag or draft card burning as a form of political protest, this activity does not convey a "particularized message" to the public. Nor, despite the fact that biomedical research often leads to the publication of useful information, would it qualify for First Amendment protection as conduct that is a "necessary precondition" of speech.[4] The few cases in which the Court has extended First Amendment protection on this ground all involve conduct necessary to speech intimately connected with democratic self-governance, such as the expenditure of money for political speech or press access to criminal trials. Being neither particularly expressive nor intimately connected to democratic self-governance, biomedical research would therefore be classified as "nonexpressive conduct" entitled to no First Amendment protection. As such, the prohibition against prior restraints on speech is

[3] The nomenclature "biomedical" obviously does not perfectly describe all research involving human subjects having no significant communicative elements, just as the term "social science" does not precisely correspond to all such research having significant communicative elements. Some biomedical research subject to IRB regulation might involve a considerable amount of verbal or written communication, and it is possible (though difficult) to imagine social science research involving human subjects with no significant communicative elements. The bigger imperfection with the social science nomenclature is that it is underinclusive: humanities and legal research also sometimes involve use of surveys and questionnaires. Thus, as used in this article, the term "biomedical research" is shorthand for all research, regardless of discipline, that has no significant expressive elements, while the term "social science research" is shorthand for all research, regardless of discipline, having significant communicative elements.

[4] *See infra* text accompanying notes 21–24.

simply inapplicable to this conduct, as is the rule against content-based speech regulation.

Part II of this Article explores the more difficult First Amendment issues arising from IRB regulation of social science research. Unlike typical biomedical research, social science research almost always involves significant communicative elements that would be classified as "speech" under the First Amendment. Nonetheless, it is uncertain whether the basic IRB requirements such as securing prior approval of the project and obtaining informed consent from the subjects would trigger any First Amendment scrutiny. These regulations do not target the communicative elements of social science research and thus are best characterized as speech-neutral laws of general applicability incidentally burdening speech. Although the Supreme Court's incidental burdens jurisprudence is confused and unsettled, I suggest that the best explanation of the seemingly incoherent pattern of decisions in this area of the law is that regulations of general applicability trigger meaningful First Amendment scrutiny only when they burden the core free speech value of democratic participation. Narrowly viewed, the communication between social scientists and their subjects ordinarily has nothing to do with this core free speech value. Viewed from a broader perspective, however, traditional interviewing techniques typically used by social scientists, such as surveys, questionnaires and conversations, are part of a medium of communication necessary for democratic self-governance. On this view, even incidental burdens on these communicative elements would trigger meaningful First Amendment scrutiny.

Although IRB regulations are speech neutral on their face and in many of their applications, they will often be applied to social science research in order to prevent harms flowing from the communicative elements of the research. Such applications would be considered content-based regulations of speech. But despite a widespread belief to the contrary, the First Amendment does not, as I shall show, generally prohibit content-based speech regulations or even render them presumptively unconstitutional. To the extent that IRB regulations seek to protect subjects from harms such as deception or bodily injury, the restriction will usually be constitutional, despite the fact that these harms are induced by speech. Content-based applications of IRB regulations are, however, more constitutionally suspect when invoked to prevent "soft" harms like stress, embarrassment and feelings of guilt arising from investigation of ideologically charged subjects such as sexual preference or abortion. Under these circumstances, IRB decisions are particularly susceptible to ideological viewpoint discrimination forbidden by the First Amendment.

Aside from applications to traditional interviewing techniques or denials of approval that reek of ideological viewpoint discrimination, even blatantly unfair or silly IRB decisions will likely be immune to successful First Amendment challenge. But this is as it should be: Although some misguided IRB decisions might interfere with social and scientific progress,

even the worst of these decisions will rarely implicate researchers' free speech rights.[5]

Part III of this Article turns to an argument against excessive IRB regulation that is much better grounded in individual rights—the claim that restrictions on research violate investigators' right of thought and inquiry. While theoretically sounder than arguments based on free speech, a major hurdle facing this claim is that the Supreme Court has been reluctant in recent years to recognize fundamental rights not specified in the text of the Constitution. Although the Court has recognized an inviolable sphere of thought and belief protected against such measures as compelled flag salutes or disclosure of political beliefs,[6] it is unlikely to extend this realm to encompass a right to research. But even if it were to do so, the Court probably would not give this right sufficient weight to protect research from most applications of IRB regulations, even extremely burdensome ones. At most, the Court would recognize a right that protects researchers against restrictions that are not only extremely burdensome but also very weakly justified.

To better expose any possible First Amendment or substantive due process problems with IRB regulations, I disregard until the end of the Article the fact that IRB regulations are imposed on research institutions not by force of law but as a condition of the receipt of federal research funds. In Part IV of the Article I consider the significance of the conditional nature of these regulations. If direct imposition of IRB regulations would not violate the First Amendment or the right of thought and inquiry, then the less intrusive measure of conditional funding could not possibly do so. More significantly, even if direct imposition of IRB regulations would violate the First Amendment or the right of thought and inquiry, these constitutional problems are obviated if the condition imposing the regulations is itself constitutional.

The doctrine of unconstitutional conditions prohibits government from attaching conditions to benefits if doing so either penalizes a constitutional

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[5] It possible that direct imposition of IRB regulations on research institutions would violate these institutions' right of academic freedom. *See generally* Keyishian v. Bd. of Regents, 385 U.S. 589, 603 (1967) (noting that "[o]ur Nation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us and not merely to the teachers concerned" and that therefore that freedom is "a special concern of the First Amendment"). Academic freedom, however, is properly understood as an institutional rather than as an individual right. *See* Robert Post, *The Structure of Academic Freedom*, *in* ACADEMIC FREEDOM AFTER SEPTEMBER 11, at 64 (Beshara Doumani ed., 2006). *See also infra* note 42. On this view institutions can waive their right to academic freedom as a condition of funding without violating any rights sounding in academic freedom of their employees. For this reason, I shall pretermit any detailed discussion of this very uncertain area of constitutional law and instead focus on individual rights that might be implicated by IRB regulations. Such a focus promises to be more fruitful because, unlike its own rights, an institution cannot waive the individual constitutional rights of its employees.

[6] *See infra* text accompanying notes 210–212.

right or induces the recipient to engage in unconstitutional activity.[7] Because IRB regulations are plainly germane to the important national interest of assuring that federal funds are spent only on ethical research, and because there is no reason to suspect that these regulations are aimed at suppressing unpopular ideas, the condition that federally supported research projects comply with IRB regulations will almost certainly be upheld as a valid funding restriction rather than a penalty. More problematic is the condition that institutions receiving any federal research support must subject even nonfederally funded research to either IRB review or some other ethical principle acceptable to the funding agency. The possibility that unregulated research at an institution might undermine the ethical standards applied in federally funded research at that institution is, however, probably sufficient to sustain the constitutionality of this condition as well. An even more difficult issue is whether the funding condition induces research institutions to violate the rights of the researchers that they employ. Though the question is close, state research institutions, acting in their capacity as employer and educator, could probably constitutionally adopt research regulations that the state acting in its sovereign capacity could not impose on researchers. Accordingly, the requirement that the funding condition not induce the recipient to violate the Constitution is probably also met, thereby curing any constitutional defects that might exist if the IRB regulations had been directly imposed.

I. BIOMEDICAL RESEARCH AND FREE SPEECH

American free speech doctrine rests on a sharp and somewhat arbitrary dichotomy between speech and conduct. As I have explained elsewhere, "speech" for First Amendment purposes is any activity that makes use of a conventional mode or medium of communication, such as talking, singing, writing or painting a picture.[8] "Conduct" is residually defined as all other human activity.[9] Such a rigid dichotomy, however, includes as speech activity having little or no free speech value (for instance, solicitation to murder) while simultaneously designating as conduct activity with considerable free speech importance (flag burning as a form of political protest, for example). To refine this blunt taxonomy, the Court has subdivided the category of speech into "protected" and "unprotected" speech,[10] and has similarly subdivided the category of conduct into "expressive"[11] and "non-

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[7] *See infra* text accompanying notes 253–256.

[8] JAMES WEINSTEIN, HATE SPEECH, PORNOGRAPHY AND THE RADICAL ATTACK ON FREE SPEECH DOCTRINE 31–32 (1999).

[9] *Id*. at 32.

[10] *See, e.g.*, Chaplinsky v. New Hampshire, 315 U.S. 568, 571–72 (1942) (observing that there are "certain well-defined and narrowly limited classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem").

[11] *See, e.g.*, United States v. Eichman, 496 U.S. 310, 315 (1990) (referring to flag burning engaged in as a means of political protest as "expressive conduct").

expressive" conduct.[12] Expressive conduct is entitled to some degree of First Amendment protection;[13] nonexpressive conduct generally receives no First Amendment protection.[14]

As will be discussed in Part II, various components of typical social science research covered by IRBs arguably qualify as "speech" for First Amendment purposes. In contrast, typical biomedical research, such as blood draws, PET scans and organ transplants, would be classified as "conduct." Biomedical research would therefore be eligible for First Amendment protection only if it qualified as "expressive conduct" or as "a necessary precondition" of protected speech. As I discuss in this Part, biomedical research qualifies as neither, and therefore warrants no First Amendment protection.

A. Biomedical Research as Expressive Conduct

As the Supreme Court has observed in delimiting the scope of expressive conduct, "[i]t is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment."[15] Thus, conduct will be deemed sufficiently communicative "to bring the First Amendment into play" only when it manifests "[a]n intent to convey a particularized message" that is likely to "be understood by those who viewed it."[16] Unlike activities such as flag or draft card burning,[17] or even nude dancing intended to convey an erotic message,[18] biomedical research will almost never manifest an intent to express a "particularized message," nor is it likely that anyone observing this activity would understand that such a message was being conveyed.[19] Accordingly, any argument that

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[12] *See* Virginia v. Hicks, 539 U.S. 113, 123 (2003) (stating that "it is Hicks' nonexpressive *conduct*—his entry in violation of the notice-barment rule—not his speech, for which he is punished as a trespasser").

[13] *See, e.g.*, United States v. O'Brien, 391 U.S. 367, 376–77 (1968).

[14] Wisconsin v. Mitchell, 508 U.S. 476, 484 (1993) (explaining that "a physical assault is not by any stretch of the imagination expressive conduct protected by the First Amendment"). As discussed below, the one narrow exception to the rule that nonexpressive conduct is entitled to no First Amendment protection is nonexpressive conduct that is an essential precondition of protected speech. *See infra* notes 21–24 and accompanying text.

[15] City of Dallas v. Stanglin, 490 U.S. 19, 25 (1989).

[16] Texas v. Johnson, 491 U.S. 397, 404 (1987) (quoting Spence v. Washington, 418 U.S. 405, 410–11 (1974)).

[17] *Johnson*, 491 U.S. 397 (flag burning); *O'Brien*, 391 U.S. at 369 (draft card burning).

[18] City of Erie v. Pap's A.M., 529 U.S. 277 (2000).

[19] A recent Supreme Court decision, *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, 126 S. Ct. 1297 (2006), demonstrates that typical biomedical research would not be considered expressive conduct. In that case, the Court rejected the claim that certain law schools' refusal to allow military recruiters access to their students because of disagreement with the armed service's policy on homosexuals in the military constituted expressive conduct. *Id.* at 1311. The Court therefore held that the

biomedical research is sufficiently expressive to warrant First Amendment protection fails "for the simple reason that scientific experimentation consists of the application, not the communication, of scientific ideas."[20]

Solomon Amendment, a federal law that required any institution of higher learning receiving federal funds to provide equal access to military recruiters, did not implicate the free speech rights of law schools wanting to refuse such access. *Id.* at 1310. The Court found that "the Solomon Amendment regulates conduct, not speech" and emphasized that it has "extended First Amendment protection only to conduct that is inherently expressive." *Id.* at 1307, 1310. The Court observed that "[u]nlike flag burning, the conduct regulated by the Solomon Amendment is not inherently expressive." *Id.* at 1310. The Court continued:

> An observer who sees military recruiters interviewing away from the law school has no way of knowing whether the law school is expressing its disapproval of the military, all of the law school's interview rooms are full, or the military recruiters decided for reasons of their own that they would rather interview someplace else.
>
> The expressive component of a law school's actions is not created by the conduct itself but by the speech that accompanies it. The fact that such explanatory speech is necessary is strong evidence that the conduct at issue here is not so inherently expressive that it warrants protection under *O'Brien*. If combining speech and conduct were enough to create expressive conduct, a regulated party could always transform conduct into "speech" simply by talking about it. For instance, if an individual announces that he intends to express his disapproval of the Internal Revenue Service by refusing to pay his income taxes, we would have to apply *O'Brien* to determine whether the Tax Code violates the First Amendment. Neither *O'Brien* nor its progeny supports such a result.

Id. at 1311.

Ordinary biomedical research is even less "inherently expressive" than is the exclusion of military recruiters from a law school due to disagreement with an armed service's policy. Irrespective of whether an observer would understand the message, the exclusion of military recruiters, unlike ordinary biomedical research, was at least meant to convey a message. Thus ordinary biomedical research is *a fortiori* not expressive conduct. *FAIR* further demonstrates, moreover, that even biomedical research engaged in as a form of protest would likely not qualify as expressive conduct. Suppose a scientist were to engage in stem cell research in order to protest the ban on federal support for such research. Like the law school excluding military recruiters because of a disagreement with military policy or a person refusing to pay income tax because of his disapproval of the IRS, in the absence of some "explanatory speech" an observer would have no way of knowing that this scientist was engaging in this research as a means of protest rather than as an ordinary research project. An observer who witnessed a scientist notoriously flouting an outright ban on a type of research would arguably have much better reason to assume that the researcher was, at least in part, engaged in a protest against the ban even without some verbal or written explanation. But this would be true of most any public violation of a law and therefore would also not be "inherently expressive." In any event, as the Court's example of the person refusing to pay his taxes as a form of protest against the IRS shows, the Court is steadfastly opposed to the notion that public violation of a law is sufficient to render such activity expressive conduct.

[20] Dana Remus Irwin, *Freedom of Thought: The First Amendment and the Scientific Method*, 2005 WIS. L. REV. 1479, 1499; *accord* James R. Ferguson, *Scientific Inquiry and the First Amendment*, 64 CORNELL L. REV. 639, 649 (1979) (claiming that scientific research "is not 'speech' at all" but "more in the nature of 'conduct'"); Gary L. Francione, *Experimentation and the Marketplace Theory of the First Amendment*, 136 U. PA. L. REV. 417, 422 (stating that "there is nothing inherent in the experimental process that allows that process to be characterized as 'expression' or 'expressive conduct'"); Barry P. McDonald, *Government Regulation or Other "Abridgments" of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, 54 EMORY L.J. 979, 993–94 (2005) (observing that at least with respect to research in the natural as opposed to social sciences, "it is often difficult to characterize such activities as being expressive or communicative[,]" and concluding therefore that such activity would be classified as "nonexpressive conduct").

B. Biomedical Research as a Necessary Precondition of Speech

Even if scientific research is ordinarily not *itself* sufficiently communicative to trigger First Amendment protection, several commentators have argued that this activity should nonetheless receive constitutional protection as an essential precondition for dissemination of information.[21] As a leading proponent of this view explains: "If the first amendment serves to protect free trade in the dissemination of ideas and information, it must also protect the necessary preconditions of speech, such as the production of ideas and information through research."[22] But as the Supreme Court observed in rebuffing a "necessary precondition of speech" argument in another context: "There are few restrictions on action which could not be clothed by ingenious argument in the garb of decreased data flow."[23] For this reason, the Court has been extremely chary of extending protection to conduct just because it is closely linked with the production of knowledge of information. Rather, the Court's basic stance is that "[t]he right to speak and publish does not carry with it the unrestrained right to gather information."[24]

The few cases extending First Amendment protection to nonexpressive conduct all involve conduct that the Court found to be a necessary precondition to speech essential to the proper functioning of democracy.[25] None of these cases involve activity such as biomedical research arguably serving a First Amendment value other than democracy, such as truth discovery in the marketplace of ideas or the flow of information needed for private deci-

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[21] *See, e.g.*, Ferguson, *supra* note 20, at 644–54; McDonald, *supra* note 20, at 1034–69; John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1217–18 (1977).

[22] Robertson, *supra* note 21, at 1217–18; *see also id*. at 1216 ("If the first amendment's purpose of assuring a free flow of information for public and private decisionmaking is to be served, then all aspects of creating, gathering, disseminating, and receiving information must be protected."). As discussed in Part II, below, contrary to Professor Robertson's premise, and as is confirmed by the very limited protection actually afforded conduct that is a "necessary precondition of speech," the commitment to "free trade in the dissemination of ideas and information" is not a core free speech value.

[23] Zemel v. Rusk, 381 U.S. 1, 16–17 (1965).

[24] *See, e.g.*, Seattle Times Co. v. Rhinehart, 467 U.S. 20, 32 (1984) (quoting *Zemel*, 381 U.S. at 16–17); *see also infra* notes 29–30 and accompanying text.

[25] For instance, in *Buckley v. Valeo*, 424 U.S. 1 (1976), the Court extended First Amendment protection to expenditure of money used to express views about political candidates or other matters of public concern. The Court found that a federal law prohibiting individuals from spending more than $1000 per year "relative to a clearly identified candidate" imposed "direct and substantial restraints on the quantity of political speech . . . . at the 'core of our electoral process and of the First Amendment freedoms.'" *Id*. at 39 (quoting Williams v. Rhodes, 393 U.S. 23, 32 (1968)). Similarly, in *Globe Newspapers v. Superior Court*, the Court recognized a right of the press to access to criminal proceedings so "that the individual citizen can effectively participate and contribute to our republican system of self government." 457 U.S. 596, 604 (1982).

sionmaking.[26] Of course, just because the Court has granted First Amendment protection only to nonexpressive conduct necessary to democratic self-governance does not mean that in the proper case it might not extend similar protection to activity necessary to promote some other free speech value. Still, it is unlikely that the Court would extend this protection to biomedical research. As I demonstrate below,[27] unlike the commitment to democratic self-governance, the First Amendment values served by the publication of ordinary biomedical research—truth discovery and dissemination of information needed for private decisionmaking—are not core First Amendment values. Given the Court's manifest reluctance to extend First Amendment protection to nonexpressive conduct under the necessary precondition to speech rationale even when core free speech interest are at stake,[28] it would be surprising if the Court were to protect conduct that is connected only to a peripheral free speech value.

Biomedical research, however, can occasionally be relevant to democratic self-governance to the extent it produces information needed for *public* decisionmaking, such as information relevant to strategies for combating epidemics or for regulating the sale of substances that might impair the public health. But even with respect to information facilitating citizens' participation in matters of public concern, the First Amendment right has been narrowly confined to places or proceedings that have traditionally been open to the public. Thus, the press does not have a right of access to prisons in order to inform the public about possible prisoner abuse.[29] Nor do Americans have a right to travel to a foreign country against the wishes of the United States government in order to become better informed about conditions there.[30] It is therefore highly unlikely that the Court would extend First Amendment protection to biomedical research because of its potential for producing information on matters of public concern.[31]

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[26] *Cf.* Robertson, *supra* note 21, at 1216 ("If the first amendment's purpose of assuring a free flow of information for public and private decisionmaking is to be served, then all aspects of creating, gathering, disseminating, and receiving information must be protected.").

[27] *See infra* notes 106–12, 115–17 and accompanying text. Because the lack of First Amendment protection for ordinary biomedical research can be demonstrated by a fairly straightforward application of free speech doctrine without resort to discussion of underlying values, I postpone an exploration of the values underlying free speech doctrine until Part II, below. In contrast to IRB regulation of biomedical research, the application of IRB regulations to social science research raises extremely difficult and novel First Amendment questions which cannot be answered by a mechanical application of doctrine but require instead an analysis informed by an understanding of the goals and purposes served by this doctrine.

[28] *See infra* notes 29–30 and accompanying text.

[29] Houchins v. KQED, Inc., 438 U.S. 1 (1978).

[30] Zemel v. Rusk, 381 U.S. 1 (1965).

[31] In addition, as discussed below, this concern, although more central than the pursuit of knowledge and truth in the marketplace of ideas or information needed for private decisonmaking, is also not a core free speech value. *See infra* notes 103–05 and accompanying text.

Those who argue that scientific research should be afforded First Amendment protection as an essential precondition of speech often rely on *Branzburg v. Hayes*,[32] a "reporter's privilege" case from the 1970s.[33] But *Branzburg* in fact shows that it is unlikely that the Supreme Court would extend First Amendment protection to biomedical research under this rationale. In *Branzburg*, several reporters argued that if they were forced to reveal confidential sources to a grand jury, other confidential sources would be deterred from furnishing publishable information, thereby restricting "the free flow of information protected by the First Amendment."[34] Writing for a majority of the Court, Justice Byron White firmly rejected the claim that reporters have a privilege not to reveal a confidential source when required by law to do so. He emphasized that while the First Amendment protects news gathering to the extent that it forbids laws discriminating against the press or which seek to control the content of what is published, the Court had consistently held that newspapers have "no special immunity from the application of general laws."[35] Justice White concluded that the only protection the First Amendment provides a reporter against revealing a confidential source in a grand jury proceeding is the protection against "[o]fficial harassment of the press undertaken not for purposes of law enforcement but to disrupt a reporter's relationship with his news sources . . . ."[36]

The argument that *Branzburg* actually offers significantly greater protection to newsgathering arises from Justice Lewis Powell's concurring opinion. *Branzburg* was a 5-4 decision, with Justice Powell joining the majority in rejecting the claim of reporter's privilege. Powell, however, wrote a concurring opinion that took a considerably more expansive view than did the majority of when the First Amendment might privilege a reporter from revealing a confidential source. Contrary to the Court's view that the First Amendment protects reporters only against bad faith attempts to interfere with confidential relationships, Powell wrote that in each case, "[t]he asserted claim to privilege should be judged on its facts by the striking of a proper balance between freedom of the press and the obligation of all citizens to give relevant testimony with respect to criminal conduct."[37] A majority opinion should control lower court decisions despite contrary language in a concurring opinion even by a Justice whose vote was needed to constitute a majority.[38] Nonetheless, according to a leading constitutional

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[32] 408 U.S. 665 (1972).

[33] *See, e.g.*, Robertson, *supra* note 21, at 1228–40.

[34] *Branzburg*, 408 U.S. at 680.

[35] *Id.* at 683 (quoting Associated Press v. NLRB, 301 U.S. 103, 132–33 (1937)).

[36] *Id.* at 707–08.

[37] *Id.* at 710 (Powell, J., concurring).

[38] *See In re* Grand Jury Subpoena (Miller), 397 F.3d 964, 971 (D.C. Cir. 2005) (citation omitted) ("Justice Powell's concurring opinion was not the opinion of a justice who refused to join the majority. He joined the majority by its terms, rejecting none of Justice White's reasoning on behalf of the major-

law casebook, "[m]ost lower court judges have followed the tenor of Justice Powell's more speech-protective concurrence."[39]

But even if *Branzburg* could properly be read as extending First Amendment protection for newsgathering beyond the narrow limits noted by the majority, this would not support further expanding this protection to cover biomedical research. The press plays a crucial role in our democracy by uncovering official wrongdoing or otherwise gathering information that the public needs to evaluate public policy matters.[40] While biomedical research may, albeit in a very different way, be as important to the lives of individuals as is newsgathering, it simply does not bear the same essential relationship to democracy or any other important, let alone core, free speech value.[41] If anything, the Court's failure in *Branzburg* or in any subsequent case to extend robust First Amendment protection to newsgathering shows that it is fanciful to suppose that it would extend such protection to something as far afield from the core of the First Amendment as is biomedical research.[42]

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ity. He wrote separately 'to emphasize' what seemed to him 'to be the limited nature of the Court's holding.' Justice White's opinion is not a plurality opinion of four justices joined by a separate Justice Powell to create a majority, it is the opinion of the majority of the Court. As such it is authoritative precedent. It says what it says. It rejects the privilege asserted by appellants."); *In re* Grand Jury Proceedings (Scarce), 5 F.3d 397, 400 (9th Cir. 1993) ("It is important to note that Justice White's opinion is *not* a plurality opinion. Although Justice Powell wrote a separate concurrence, he also signed Justice White's opinion, providing the fifth vote necessary to establish it as the majority opinion of the court."). *But see* McKoy v. North Carolina, 494 U.S. 433, 462–63 n.3 (1990) (Scalia, J., dissenting) (arguing that where an "individual Justice is [] needed for the majority," then the Court's "opinion is *not* a majority opinion except to the extent that it accords with his views").

[39] KATHLEEN M. SULLIVAN & GERALD GUNTHER, CONSTITUTIONAL LAW 1479 (15th ed. 2004). *But see In re* Grand Jury Subpoena (Miller), 297 F.3d 964; *In re* Grand Jury Proceedings (Scarce), 5 F.3d 397. And contrary to commentators and lower court decisions that have relied on Justice Powell's balancing test, the Court has subsequently referred to *Branzburg* as within a line of decisions "holding that generally applicable laws do not offend the First Amendment simply because their enforcement against the press has incidental effects on its ability to gather and report the news." Cohen v. Cowles Media Co., 501 U.S. 663, 669 (1991).

[40] *See infra* notes 134–35 and accompanying text.

[41] For this reason, to the extent that IRBs regulate biomedical research, Hamburger's comparison of IRBs to a hypothetical Newspaper Review Board is inapt. Hamburger, *supra* note 2, at 307–08. The analogy is much more telling, however, with respect to IRB regulation of social science research using traditional interviewing methods such as surveys, questionnaires and oral questions. *See infra* notes 126–40 and accompanying text.

[42] Although biomedical research is not itself sufficiently communicative or sufficiently related to core First Amendment activity to be considered speech within the ambit of the First Amendment, direct application of IRB regulations to biomedical research by force of law might arguably violate the constitutional right of academic freedom. *See, e.g.*, Keyishian v. Bd. of Regents, 385 U.S. 589, 603 (1967); Sweezy v. New Hampshire, 354 U.S. 234, 261 (1957) (Frankfurter, J., concurring). But even if imposition of IRB regulations by force of law would violate the research institution's constitutional right of academic freedom, imposition of these regulations as a condition of receipt of federal research funds would not. This is because academic freedom is an institutional right, not a right of the individual researchers, and thus can be waived by the institution. As Robert Post has explained:

C. The Doctrinal Consequences of the Lack of First Amendment Coverage for Biomedical Research

The classification of biomedical research as nonexpressive conduct not eligible for First Amendment protection as a necessary precondition of speech has enormous doctrinal consequences. It means that biomedical research will be treated like the great residuum of human activity outside the ambit of the First Amendment. As with all other such conduct, government can regulate biomedical research free of the heightened scrutiny triggered when government regulates activity within the purview of the First Amendment.[43] Similarly, special restrictions on government's power to regulate First Amendment activity—such as the prohibition against prior restraints or the rule against content-based regulations—are simply inapplicable. Accordingly, with respect to biomedical research, the argument that IRBs constitute an unconstitutional prior restraint cannot get off the ground. For the same reason, Professor Hamburger's argument that, "although the

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> [Academic freedom] may be asserted in particular cases by individual faculty, but it does not protect interests that are defined by reference to the perspectives and horizons of individual professors. Rights of academic freedom are instead designed to facilitate the professorial self-regulation of the professoriat, so that academic freedom safeguards interests that are constituted by the perspective and horizon of the corporate body of the faculty. The function of academic freedom is not to liberate individual professors from all forms of institutional regulation, but to ensure that faculty within the university are free to engage in the professionally competent forms of inquiry and teaching that are necessary for the realization of the social purposes of the university.

Post, *supra* note 5, at 64.

Thus in the view of the Association of American University Professors ("AAUP"), an organization dedicated to protecting academic freedom, because "scholars have [no] right to be provided with federal funds to support their research without providing assurances that they will protect their human subject," then "plainly no academic freedom is violated by the imposition of that condition on federal research funds." *Protecting Human Beings: Institutional Review Boards and Social Science Research*, ACADEME, May–June 2001, at 55, 58–59. A more recent AAUP report, in contrast, describes the IRB procedures as an "obvious potential threat to academic freedom." *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME, Sept.–Oct. 2006, at 95, 96 [hereinafter *Research on Human Subjects*]. The focus of this report, however, is not on IRB application to biomedical research, but rather on IRB regulation of "research whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places," which the report recommends be exempt from IRB review. *Id*. at 97. As discussed in detail below, unlike IRB regulation of typical biomedical research, application of IRB regulation to social science research consisting entirely of interviews and surveys raises substantial free speech issues. *See* text accompanying *infra* notes 126–40. The AAUP report notes Professor Hamburger's argument that IRB regulations constitute an unconstitutional prior restraint, but takes no position on this issue. *See Research on Human Subjects*, *supra*, at 95.

[43] Professor Hamburger erroneously states that even if research is deemed nonexpressive conduct, it will be subject to the First Amendment scrutiny applied by the Court in *United States v. O'Brien*, 391 U.S. 367, 377 (1968). But as *O'Brien* itself emphasized, only activity sufficiently expressive to be classified as "expressive conduct" is entitled to this modest level of scrutiny. *See id.* at 376 (stating that "[w]e cannot accept the view that an apparently limitless variety of conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea[,]" but assuming that the "communicative element" in the draft card burning at issue was "sufficient to bring into play the First Amendment"). *See supra* note 14 and accompanying text. As we have seen, biomedical research is not sufficiently expressive to be considered expressive conduct.

IRB regulations appear to be focused on conduct, they discriminate on the basis of content"[44] is a First Amendment non sequitur.[45]

II. SOCIAL SCIENCE RESEARCH AND FREE SPEECH

Unlike biomedical research, which is no more expressive than most other types of human conduct, social science research typically involves communicative elements such as interviews, surveys, conversations, or

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[44] The "content discrimination" that Hamburger identifies is threefold: (1) that IRB regulations apply to "research at research institutions . . . while simultaneously leaving the same conduct unconstrained if done not as part of such research" and "thereby discriminate against inquiry and publication"; (2) that in defining research as a "systematic investigation" designed to produce "generalizable knowledge," the regulations "discriminate against those who pursue the modern, empirical conception of knowledge"; and (3) in requiring IRBs to evaluate the risks and benefits of research "the regulations thereby subject methodology to a process that inevitably discriminates against unconventional or unpopular approaches." Hamburger, *supra* note 2, at 307–10. Hamburger argues that in discriminating in these ways, the IRB regulations "target speech." *Id.* at 306. This argument is at war with the basic premise that activity classified as nonexpressive conduct is not sufficiently expressive to warrant any First Amendment scrutiny. The claim that IRB regulation unconstitutionally discriminates against inquiry and publication reduces essentially to the argument considered and rejected above in Part I.B that because research often leads to publication it should be specially protected by the First Amendment as a "necessary precondition of speech." The only respect in which Hamburger's argument differs from a straight ahead "necessary precondition" argument is the claim that the regulation not only burdens research but *discriminates* against this activity. But unless an activity is within the ambit of First Amendment coverage, which, as we have seen, is not the case with respect to biomedical research, no First Amendment issue is raised by discrimination against this activity. *Cf.* Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue, 460 U.S. 575 (1983) (holding that a tax that singled out the press for special treatment violated the First Amendment). For the same reason, the "discrimination" against those "who pursue the modern, empirical conception of knowledge" does not raise a First Amendment issue: Because biomedical research is nonexpressive conduct, the government has virtual carte blanche to define the scope of the activity it wishes to regulate without running afoul of the prohibition against content discrimination.

[45] Arguably, even when regulating nonexpressive conduct, the government might be constitutionally prohibited from defining the regulated subject matter according to some criterion that the First Amendment forbids, such as political ideology. *See* Wisconsin v. Mitchell, 508 U.S. 476, 484–86 (1993) (suggesting that a law regulating nonexpressive conduct might violate the First Amendment if it were justified solely as punishing a defendant for holding "abstract beliefs"); *see also* James Weinstein, *Hate Crime and Punishment: A Comment on* Wisconsin v. Mitchell, 73 OR. L. REV. 345, 348–60 (1994). Thus, a law that subjected only research by members of the Communist Party to IRB scrutiny would probably violate the First Amendment. It would be fanciful, however, to suppose that in applying IRB regulations only to research at research institutions, the federal government was motivated by a desire to suppress publication; or that in defining research to mean "systematic investigation" designed to produce "generalizable knowledge" it was expressing hostility towards the "modern, empirical conception of knowledge"; or that its purpose in requiring IRBs to evaluate the risks and benefits of research was to suppress "unconventional or unpopular" research methodologies. Hamburger, *supra* note 2, at 308–10. Indeed, one of the instances of "discrimination" that Hamburger decries is actually a speech protective limitation on the scope of the IRB regulations. Thus the limitation to "systematic investigation" designed to produce "generalizable knowledge" exempts interaction between researchers and their students in the classroom. *See* National Science Foundation, Frequently Asked Questions and Vignettes, Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research, http://nsf.gov/bfa/dias/policy/hsfaqs.jsp (last visited Nov. 9, 2006).

written and oral directions connected with experiments or tests, all of which would be considered "speech" for First Amendment purposes.[46] Despite the existence of these communicative elements, however, it is not clear that application of IRB regulations to social science research would trigger meaningful protection for this speech.[47] This uncertainty arises because IRB regulations are rules of general applicability that, on their face at least,[48] apply to research despite, not because of, its communicative elements: It is the researchers' use of human subjects that triggers the application of the regulations, not the choice to interview rather than to perform invasive procedures on the subjects. Of all the difficult areas of free speech jurisprudence, the doctrine regarding the application of laws of general applicability to speech is perhaps the most confused and uncertain.

A. *The Uncertain Law of Incidental Burdens on First Amendment Activity*

What makes the law of incidental burdens particularly confusing is that while some Supreme Court decisions appear to apply meaningful First Amendment scrutiny to laws of general applicability that only incidentally burden expression, other cases expressly apply no First Amendment scrutiny to such laws. A well known case applying First Amendment scrutiny is *United States v. O'Brien*.[49] In that case, an anti-war activist who burned his draft card as a means of political protest was convicted under a federal law that prohibited forging, altering, destroying or mutilating a draft card. The Court explained that "when 'speech' and 'non-speech' elements are combined in the same course of conduct," the government must show a "sufficiently important governmental interest in regulating the nonspeech element" in order to justify the "incidental limitations" on the speech element.[50] Although finding that the government's interest in ensuring the proper functioning of the selective service system was a sufficiently impor-

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[46] *See* McDonald, *supra* note 20, at 994–95 (observing that "whether a social scientist is conducting a survey via the use of a questionnaire or a child psychologist is interviewing children as part of an experiment, such empirical methods of investigation will often have a significant expressive component").

[47] *Cf. id.* ("To the extent the regulation of such research can reasonably be characterized as a regulation of 'expressive or communicative activities' because of the research's significant characteristics in this regard, it would most likely be subject to First Amendment scrutiny.").

[48] As will be discussed below, although facially speech neutral, application of IRB regulations will often focus on the communicative impact of the speech and thus are content-based as applied. *See infra* text accompanying notes 173–175. However, because there are also many content-neutral applications of IRB regulations to social science research, *see infra* notes 143–47 and accompanying text, it is useful as a first step in the analysis to consider IRB regulations as a law of general applicability that incidentally burdens speech. Another reason for applying this framework, at least as an initial cut at the problem, is that even in cases involving a content-based application of a law or a speech-neutral law of general applicability, the Court continues to attach significance to the fact that the law is one of general applicability. *See* FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990); *infra* notes 73–83 and accompanying text (discussing *Trial Lawyers Ass'n*).

[49] 391 U.S. 367 (1968).

[50] *Id.* at 376.

tant speech neutral reason to justify the incidental burden on O'Brien's First Amendment rights, the Court applied what has subsequently been referred to as "intermediate scrutiny"[51] to the regulation as applied to this expressive conduct.[52] Several other cases have similarly applied this scrutiny to incidental burdens on expressive activity imposed by application of laws of general applicability.[53] Under this approach, the application of IRB regulations to typical social science research would seemingly trigger meaningful First Amendment scrutiny.

In contrast to its approach in *O'Brien*, the Court on other occasions has refused to apply First Amendment scrutiny to the application of generally applicable laws burdening expressive activity. For instance, in *Arcara v. Cloud Books, Inc.*,[54] the Court held that the application of a public health law, which authorized the closure of any premises in which illegal sex acts take place, to an adult book store where such acts occurred triggered no First Amendment scrutiny.[55] The Court reached this conclusion despite the burden that the closure put on the First Amendment activity of bookselling.[56] The Court explained that the First Amendment scrutiny applied in *O'Brien* was warranted only where it is the speech element that "drew the legal remedy in the first place,"[57] not activity such as the sexual conduct that "manifests absolutely no element of protected expression."[58] Other cases have similarly refused to apply any First Amendment scrutiny to the application of laws of general applicability to expressive activity.[59] Under this approach, since it is the use of human subjects, not the communication with them, that "dr[aws] the legal remedy" of IRB regulation, the application of these regulations to social science research would not trigger First Amendment scrutiny.[60]

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[51] *See, e.g.*, Turner Broad. Sys. v. FCC, 520 U.S. 180, 189 (1997).

[52] *O'Brien*, 391 U.S. at 377–82.

[53] *See, e.g.*, City of Erie v. Pap's A.M., 529 U.S. 277, 292 (2000); Barnes v. Glen Theatre, Inc., 501 U.S. 560, 567 (1991); United States v. Albertini, 472 U.S. 675, 688–89 (1985); Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 294, 298–99 (1984).

[54] 478 U.S. 697 (1986).

[55] *Id*. at 707.

[56] *Id*. at 706.

[57] *Id*.

[58] *Id*. at 705.

[59] *See, e.g.*, Rumsfeld v. Forum for Academic and Institutional Rights, Inc., 126 S. Ct. 1297 (2006); FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990); Cohen v. Cowles Media Co., 501 U.S. 663 (1991).

[60] It could be argued, however, that as in *O'Brien* and unlike in *Arcara*, the activity that "dr[aws] the legal remedy" of IRB jurisdiction is inextricably intertwined with the expressive element. Just as it was impossible for O'Brien to burn his draft card without destroying or altering it in violation of the statute, it would typically be impossible for social scientists to engage in research without using human subjects. In contrast, it was quite possible for the adult book store owner to sell books without allowing his premises to be used for illegal sex acts. Given the impossibility of separating the speech and non-speech elements from the activities that bring social science researchers under the jurisdiction of the

Which approach the Court would take with respect to the application of IRB regulations to social science research is thus uncertain.[61] Geoffrey Stone, however, offers some helpful insights into the Court's incidental burdens jurisprudence that can be usefully applied to our inquiry. Professor Stone begins by observing that the number of generally applicable laws that could incidentally burden free speech is "virtually limitless."[62] Accordingly, in order to avoid the "nightmare of judicial administration" that would result if such application of facially speech neutral laws were subject to First Amendment scrutiny, the Court "starts from the presumption that

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IRB, application of IRB regulations to this activity should, the argument continues, be subjected to intermediate scrutiny. While the preceding argument does distinguish *Arcara* from *O'Brien* and thus offers some support for applying intermediate scrutiny to IRB regulation of social science research, it is not by any means conclusive. Except in cases in which the speech element is easily severable from the regulated conduct, such an approach would commit the Court to applying First Amendment scrutiny to the application of any law that incidentally burdened any type of activity that could conceivably be characterized as speech within the meaning of the First Amendment. For instance, under this approach the application of the antitrust laws to two competitors who share with each other the prices at which they plan to sell their products would be subject to First Amendment scrutiny, for here the expressive activity (communication of the information) is, like the draft card burning in *O'Brien*, inseparable from the activity that "drew the legal remedy." The same would be true of anyone providing inside information or filing a proxy statement in violation of the securities laws, or of a physician who commits malpractice by giving erroneous medical advice to a patient. It is certain, however, that the Court would not apply First Amendment scrutiny to applications of generally applicable laws such as these. *See, e.g.*, FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990); *see also infra* notes 73–83 and accompanying text (discussing *Trial Lawyers Association*). In addition, whether speech is inextricably bound up with nonexpressive conduct is a slippery concept not easily susceptible to judicial administration.

[61] What is certain is that the criteria for overcoming this presumption against First Amendment scrutiny cannot be captured by any one single factor, particularly one as mechanistic as whether the activity that "drew the legal remedy" is inextricably bound up with conduct with a significant expressive element. Perhaps the Court in *Arcara* was groping towards a distinction between *symbolic conduct*, such as the draft card and flag burning as a means of political protest, on the one hand, and speech that is an essential part of a larger course of conduct, such as the economic boycott involved in *Trial Lawyers Association*, 493 U.S. at 411. Given the strict requirement for qualification as symbolic conduct, *see supra* notes 16, 19 and accompanying text, the Court can bestow the modest First Amendment protection afforded by the *O'Brien* test on all such expression without opening the "floodgates" that would occur if it offered similar protection to all expression burdened by the application of laws of general applicability. *Accord* Michael C. Dorf, *Incidental Burdens on Fundamental Rights*, 109 HARV. L. REV. 1175, 1208 (1996) ("If one finds that the distinction between acts that facilitate speech and acts that are intertwined with speech is an inadequate basis upon which to build an incidental burden doctrine, one response would be to apply *O'Brien* scrutiny to both categories. But if that were done, the domain of *O'Brien* would be too broad, because a virtually limitless number of regulable activities can be 'communicative' (in the sense of intertwined with *or* facilitative of speech).").

[62] Geoffrey R. Stone, *Content-Neutral Restrictions*, 54 U. CHI. L. REV. 46, 105 (1987); *accord* Dorf, *supra* note 61, at 1208 (noting that "a virtually limitless number of regulable activities can be 'communicative' (in the sense of intertwined with *or* facilitative of speech)"); Frederick Schauer, *Cuban Cigars, Cuban Books, and the Problem of Incidental Restrictions on Communications*, 26 WM. & MARY L. REV. 779, 784 (1985) ("To be concerned significantly, in a constitutional sense, with incidental effects is to be committed to judicial scrutiny of an enormous range of government decisions."). For a helpful discussion of the law of incidental burdens as it relates to scientific research, see McDonald, *supra* note 20, at 1034–69.

such laws raise no first amendment issue."[63] Stone suggests that the "pivotal" factor for deciding whether the presumption should be rebutted[64] is "the extent to which the challenged restriction actually diminishes the opportunities for free expression."[65] This observation is correct so far as it goes. But whether an incidental restriction on expressive activity actually diminishes opportunities for free expression does not depend solely on *the degree* to which the expressive activity is burdened, the aspect on which Stone's analysis focuses. More subtly, but also in my view more crucially, this determination depends on the First Amendment *values* implicated by the restriction in question.[66] The importance of the nature of the speech burdened by a general law is demonstrated by the radically different treatment of economic boycotts in two Supreme Court cases in which First Amendment protection was claimed by those engaged in a concerted refusal to deal.

In the first case, *NAACP v. Claiborne Hardware Co.*,[67] the Court reversed a judgment obtained by several white merchants under state antitrust

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[63] Stone, *supra* note 62, at 108; *accord* Schauer, *supra* note 62, at 789 ("Under most circumstances a burden on speech incidental to a generally applicable regulation not focused on communication will be tested against standards not significantly more stringent than minimal rationality. . . ."). As the Court stated in holding that application of the National Labor Relations Act's requirement to engage in collective bargaining with labor organizations to press organizations did not violate the First Amendment: "The business of the Associated Press is not immune from regulation because it is an agency of the press. The publisher of a newspaper has no special immunity from the application of general laws." Associated Press v. NLRB, 301 U.S. 103, 132 (1937); *see also* Cowles Media Co., 501 U.S. at 669–70 (referring to the "well-established line of decisions holding that generally applicable laws do not offend the First Amendment simply because their enforcement against the press has incidental effects on its ability to gather and report the news").

[64] Justices Antonin Scalia and Clarence Thomas would make this presumption irrebuttable. *See* City of Erie v. Pap's A.M., 529 U.S. 277, 307–08 (2000) (Scalia, J., concurring, joined by Thomas, J.) (quoting Barnes v. Glen Theatre, Inc., 501 U.S. 560, 572 (1991) (Scalia, J., concurring) (stating that "as a general law regulating conduct and not specifically directed at expression, it is not subject to First Amendment scrutiny at all.")). As Justice Scalia explained in an earlier case, this approach "ensures that the government does not act to suppress communication, without requiring that all conduct-restricting regulation (which means in effect all regulation) survive an enhanced level of scrutiny." *Barnes*, 501 U.S. at 578–79.

[65] Stone, *supra* note 62, at 59. Professor Stone is speaking here of all content-neutral regulations, including "time, place and manner" regulations of speech, not just of incidental burdens imposed on speech by laws of general applicability.

[66] As I have explained in a previous article, a more extensive study of the Court's decisions dealing with content-neutral regulations of speech, despite the talk of heightened or intermediate scrutiny, truly content-neutral laws are in fact subject to meaningful scrutiny only "if the challenger can make a clear showing that the law will likely have a real and substantial negative impact on public discourse, especially on the ability on an individual speaker to participate in that discussion." James Weinstein, *Database Protection and the First Amendment*, 28 U. DAYTON L. REV. 305, 336 (2002); *see also* Eugene Volokh, *Speech as Conduct: Generally Applicable Laws, Illegal Courses of Conduct, "Situation-Altering Utterances," and Uncharted Zones*, 90 CORNELL L. REV. 1277, 1338–39 (2005) (arguing that in assessing the constitutionality of content-based application of speech neutral laws of generally applicability, courts should consider, among other factors, "the value of the speech").

[67] 458 U.S. 886 (1982).

laws against the National Association for the Advancement of Colored People ("NAACP"). The NAACP had engaged in a secondary boycott against the merchants intended to pressure elected officials to agree to a list of demands for racial equality and integration.[68] The Court explained that although the boycott involved constitutionally protected activity,[69] this did not end the inquiry. Citing *O'Brien*, the Court explained that because government has a strong interest in combating the "disruptive" economic effects of boycotts, it can ordinarily regulate such activity "though such regulation may have an incidental effect on rights of speech and association."[70] In this case, however, the Court refused to allow the state to apply its prohibition against secondary boycotts to the "peaceful political activity"[71] at issue, emphasizing that "expression on public issues 'has always rested on the highest rung of the hierarchy of First Amendment values.'"[72]

In the second case, *FTC v. Superior Court Trial Lawyers Association*,[73] the Court refused to extend any constitutional protection to an economic boycott by a group of lawyers who agreed not to represent indigent criminal defendants in the District of Columbia Superior Court until the District of Columbia government increased their compensation for representing these defendants.[74] The Court of Appeals for the D.C. Circuit, having found the boycott "to convey a political message to the public at large"[75] and thus to "'contain an element of expression warranting First Amendment protection,'"[76] applied the *O'Brien* test and held that the Sherman Act's rule of per se illegality for price fixing agreements could not be constitutionally applied to this boycott.[77] In reversing the Court of Appeals, the Supreme Court noted that "[e]very concerted refusal to do business with a potential customer or supplier has an expressive component," just as "the most blatant, naked price-fixing agreement is a product of communication."[78] The Court explained, however, that that this was "surely not a reason for viewing [these activities] with special solicitude."[79] And in a dictum that has special relevance to our inquiry, the Court warned that a "rule that requires

[68] *Id.* at 889.

[69] *Id.* at 907–11.

[70] *Id.* at 912.

[71] *Id*. at 913.

[72] *Id.* at 913 (quoting Carey v. Brown, 447 U.S. 455, 467 (1980)). The Court explained that such activity is "'more than self-expression; it is the essence of self-government.'" *Id.* (quoting Garrison v. Louisiana, 379 U.S. 64, 74–75 (1964)).

[73] 493 U.S. 411 (1990).

[74] *Id.* at 414.

[75] *Id*. at 421.

[76] *Id*. at 420 (quoting Superior Court Trial Lawyers Ass'n v. FTC, 856 F.2d 226, 248 (D.C. Cir. 1988)).

[77] *Id.* at 421.

[78] *Id.* at 431.

[79] *Id.* at 431.

courts to apply the antitrust laws 'prudently and with sensitivity' whenever an economic boycott has an 'expressive component' would create a gaping hole in the fabric of those laws."[80]

The denial of any First Amendment coverage to the expressive activities in *Trial Lawyers' Association* has important implications for whether the Court would apply First Amendment scrutiny to IRB regulations to social science research. First, it belies the suggestion that just because social science involves expressive elements, any regulation of this activity triggers heightened First Amendment scrutiny. In addition, it is significant that although the regulation at issue in that case was speech-neutral on its face, its application to the lawyers' boycott was content based. As the Court recognized, it was communicative elements of the boycott that caused the harm to which the prohibition was addressed.[81] Accordingly, *Trial Lawyers' Association* raises the possibility that even content-based applications of IRB regulations will not be subject to First Amendment scrutiny. Finally, and most importantly, taken together with *Claiborne Hardware*, *Trial Lawyers' Association* suggests that laws of general applicability are subject to First Amendment scrutiny only when they burden expression "on the highest rung of the hierarchy of First Amendment values."[82] At a minimum, the radically different treatment of the boycotts involved in these two cases shows that the free speech values impaired by the application of the generally applicable law is a crucial factor in determining if any First Amendment scrutiny is warranted.[83]

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[80] *Id.* at 431–32.

[81] *Id.* For a useful discussion emphasizing the distinction between content-neutral and content-based applications of speech neutral laws, see Volokh, *supra* note 66, at 1284 (observing that "a generally applicable law is content-based *as applied*—when speech triggers the law because of the harms that may flow from what the speech says").

[82] NAACP v. Claiborne Hardware Co., 458 U.S. 886, 913 (1982) (quoting Carey v. Brown, 447 U.S. 455, 467 (1980)). In contrast, *City of Erie v. Pap's A.M*, 529 U.S. 277 (2000), suggests that incidental burdens on even marginal free speech values imposed by laws of general applicability might trigger some modest level of First Amendment scrutiny. That case upheld against First Amendment challenge a ban on public nudity as applied against erotic nude dancing in "nude dancing establishments," but only after subjecting the ban to the intermediate scrutiny set forth in *O'Brien*. *Id.* at 282–302. The Court noted that although "[b]eing 'in a state of nudity' is not an inherently expressive condition," the erotic nude dancing at issue "is expressive conduct, although . . . only within the outer ambit of the First Amendment's protection." *Id.* at 289. Note, however, that unlike the expressive elements of social science research, erotic nude dancing is an example of "symbolic conduct," a category of expression that I have suggested that the Court has treated with more First Amendment solicitude than other forms of conduct containing expressive elements. *See supra* note 61.

[83] In attempt to reconcile the two holdings, the Court in *Trial Lawyers Association* explained that it was "of course, clear that the association's efforts to publicize the boycott, to explain the merits of its cause, and to lobby District officials to enact favorable legislation—like similar activities in *Claiborne Hardware*—were activities that were fully protected by the First Amendment," and that the only activity prohibited by the FTC's order was "a concerted refusal by [the association's lawyers] to accept any further assignments until they receive an increase in their compensation." *Trial Lawyers Ass'n*, 493 U.S. at 426. It is far from "clear," however, that one has a First Amendment right to publicize an illegal course of activity. But even if the *Trial Lawyers Association* boycotters had a right to engage in all of the

Accordingly, to properly analyze the First Amendment issues raised by application of IRB regulations to social science research, it is necessary to examine the values underlying American free speech doctrine and to determine where in what the Court in *Claiborne Hardware* called the "hierarchy of First Amendment values"[84] expression involved in typical social science research falls.

B. Free Speech Values

Courts and commentators generally agree that the constitutional protection of free speech serves one or more of the following values: "advancing knowledge and 'truth' in the 'marketplace of ideas,' facilitating representative democracy and self-government, and promoting individual autonomy, self-expression and self-fulfillment."[85] But which of these values actually informs free speech doctrine and which, if any, is a core value are extremely contentious questions. Careful examination of the pattern of the decided decisions, however, suggests the following hierarchy of values: The core free speech norm is a commitment to the individual right to participate in democratic self-governance. More instrumental democratic considerations, such as assuring that people have adequate information to make decisions on matters of public concern, play an important but secondary role. The marketplace of ideas rationale is a peripheral norm, while any broad, undifferentiated autonomy concern is not even a part of the mix. I will first defend this view and then suggest what implications it has for the protection of social science research.

1. Democracy and Public Discourse.—While there is vigorous disagreement about what other values might also be central to the First Amendment, there is "practically universal agreement" that at least one such core norm is the commitment to democratic self-governance.[86] In its

communicative activities peripheral to the concerted refusal to deal itself, they did not share the First Amendment right of the boycotters in *Claiborne Hardware* to engage in the expressive and associational elements constituting the concerted activity.

[84] 458 U.S. at 913.

[85] SULLIVAN & GUNTHER, *supra* note 39, at 987.

[86] Mills v. Alabama, 384 U.S. 214, 218 (1966) ("Whatever differences may exist about interpretations of the First Amendment, there is practically universal agreement that a major purpose of that Amendment was to protect the free discussion of governmental affairs."); *see also Claiborne Hardware*, 458 U.S. at 913 (explaining that because "speech concerning public affairs . . . is the essence of self-government," such expression "has always rested on the highest rung of the hierarchy of First Amendment values" (citations omitted)); Roth v. United States, 354 U.S. 476, 484 (1957) ("The protection given speech and press was fashioned to assure unfettered interchange of ideas for the bringing about of political and social changes desired by the people."); Stromberg v. California, 283 U.S. 359, 369 (1931) ("The maintenance of the opportunity for free political discussion to the end that government may be responsive to the will of the people and that changes may be obtained by lawful means, an opportunity essential to the security of the Republic, is a fundamental principle of our constitutional system."); Whitney v. California, 274 U.S. 357, 375 (1927) (Brandeis, J., concurring) ("Those who won our independence believed that . . . public discussion is a political duty; and that this should be a fundamental

narrowest but most powerful conception, this core free speech precept recognizes the right of every individual to participate freely and equally in the speech by which we govern ourselves, expression that the Court and commentators have referred to as "public discourse."[87] As Learned Hand long ago observed, "public opinion" is "the final source of government in a democratic state."[88] If the government prevents people from freely participating in the conversation by which this opinion is formed, the people are no longer self-governing.[89] Thus to the extent it assures the opportunity for democratic participation, free speech is not just instrumental to but constitutive of democracy,[90] or as the Supreme Court has characterized it, "the essence of self-government."[91]

The opportunity for each citizen to participate in public discourse is vital to the legitimacy of the entire legal system.[92] If an individual is excluded from participating in public discourse because the government disagrees with his views or finds his ideas too disturbing or too dangerous, any decision taken as a result of that discussion would lack legitimacy, and if imposed on that speaker by coercive measures, would be tyrannical. This concern for legitimacy thus renders American free speech doctrine radically egalitarian, at least in the formal sense. And it is this right to equal participation that explains why the First Amendment prohibits government from regulating the content of speech—though not, as some have erroneously claimed,[93] the content of virtually all speech—but rather the content of public discourse.

This right to participate equally in public discourse free of government imposed content restriction is a truly fundamental individual right that may be infringed, if at all, only in truly extraordinary circumstances. For in-

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principle of the American government."); Nixon v. Shrink Mo. Gov't PAC, 528 U.S. 377, 410–11 (2000) (Thomas, J., dissenting) ("I begin with a proposition that ought to be unassailable: Political speech is the primary object of First Amendment protection."); Cass R. Sunstein, *Half-Truths of the First Amendment*, 1993 U. CHI. LEGAL F. 25, 25 (observing that "whatever else it is about, the First Amendment is at least partly designed to create a well-functioning deliberative democracy.").

[87] *See, e.g.*, Hustler Magazine, Inc. v. Falwell, 485 U.S. 46, 55 (1988); Cohen v. California, 403 U.S. 15, 22 (1971); Robert C. Post, *The Constitutional Concept of Public Discourse: Outrageous Opinion, Democratic Deliberation, and* Hustler Magazine v. Falwell, 103 HARV. L. REV. 601 (1990).

[88] Masses Publ'g Co. v. Patten, 244 F. 535, 540 (S.D.N.Y. 1917).

[89] As James Madison explained at the founding of this Nation, under our constitutional scheme "[t]he people, not the government, posses[s] the absolute sovereignty," James Madison, *Virginia Resolutions*, *in* 4 JONATHAN ELLIOT, DEBATES IN THE SEVERAL STATE CONVENTIONS ON THE ADOPTION OF THE FEDERAL CONSTITUTION 569–70 (1836), and therefore "the censorial power is in the people over the Government, and not in the Government over the people." 4 ANNALS OF CONG. 934 (1794).

[90] RONALD DWORKIN, FREEDOM'S LAW: THE MORAL READING OF THE AMERICAN CONSTITUTION 200 (1996).

[91] Garrison v. Louisiana, 379 U.S. 64, 74–75 (1964).

[92] Robert C. Post, *Racist Speech, Democracy, and the First Amendment*, 32 WM. & MARY L. REV. 267, 282 (1991).

[93] *See infra* notes 182–88 and accompanying text.

stance, even if the government could persuasively demonstrate that protests in the United States against the war in Iraq both dispirit our troops and encourage the insurgents to continue fighting, antiwar protests could still not be forbidden on these grounds. The vital importance of this core participatory right also explains why incidental restrictions on public discourse such as draft card burning as a means of political protest warrant First Amendment scrutiny, while incidental restriction on other forms of expression, such as the communication of price information between competitors, does not. Similarly, as discussed above,[94] because expenditure of money used to express views about political candidates or other matters of public concern is a "necessary precondition" to speech "at the core of our electoral process and of the First Amendment freedoms,"[95] it is one of the few forms of nonexpressive conduct that receives First Amendment protection.

It is not just the content of the speech, however, that determines whether it will be highly protected as public discourse. As Robert Post has explained, in modern democratic societies certain modes of communication form "a structural skeleton that is necessary, although not sufficient, for public discourse to serve the constitutional value of democracy."[96] For this reason, "it is assumed that if a medium [is] constitutionally protected by the First Amendment, each instance of the medium would also be protected."[97]

So far we have been focusing on the right of *speakers* to participate in democratic self-governance. Audience interests are a core concern too, but only in the space created by the important limitation on *the reasons* that government may regulate speech. Specifically, when addressing us as the

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[94] *See supra* note 25 and accompanying text.

[95] Buckley v. Valeo, 424 U.S. 1, 39 (1976) (citing Williams v. Rhodes, 393 U.S. 23, 32 (1968)) (internal quotation marks and citation omitted).

[96] Robert C. Post, *Recuperating First Amendment Doctrine*, 47 STAN. L. REV. 1249, 1276 (1995).

[97] *Id*. at 1253. The importance of the medium in which a given instance of speech occurs to the process of democratic self-governance is in my view the best explanation of why the Supreme Court rigorously protects nudity in film and cable television—media that are in its view part of the "structural skeleton" of public discourse—but not in live performances by erotic dancers on the stage of a "strip club." *Compare* Playboy Entm't Group, Inc. v. United States, 529 U.S. 803 (2000) (finding that a federal statute requiring cable television operators to fully scramble or otherwise limit sexually-oriented programming violated the First Amendment), *with* City of Erie v. Pap's A.M., 529 U.S. 277 (2000) (finding that the application of a city ordinance banning public nudity to a nude dancing establishment did not violate the First Amendment). As I have explained elsewhere, however, although there are good reasons "to presume that any particular message in a medium essential to democratic communication is in fact part of this democratic dialogue," this presumption is rebuttable. *See* James Weinstein, *Speech Categorization and the Limits of First Amendment Formalism: Lessons from* Nike v. Kasky, 54 CASE W. RES. L. REV. 1091, 1121 (2004) [hereinafter Weinstein, *Speech Categorization*]. For instance, even though newspaper editorial columns are undoubtedly an essential medium for public discourse, a journalist who used such a column to tout a stock that he secretly purchased would have no First Amendment immunity against the laws forbidding stock manipulation. *See* United States v. Wenger, 427 F.3d 840 (10th Cir. 2005). Similarly, despite the importance of film as a medium of democratic communication, legally obscene pornographic films are nonetheless entitled to no First Amendment protection. *See* Paris Adult Theatre I v. Slaton, 413 U.S. 49 (1973).

ultimate governors in a democratic society, government may not limit speech because it believes that this speech will lead us to make unwise or even disastrous social policy decisions. To regulate speech for this reason would violate the core democratic norm that the people are the ultimate sovereigns.[98]

For three reasons, this right to participate in democratic self-governance, both as a speaker and audience, is properly referred to as the core free speech norm. First, this norm explains the pattern of decided decisions far better than does any other contender.[99] In addition, regulations that infringe this right of free and equal participation are invariably held unconstitutional even if the government can show that serious harm might result if the speech is left unregulated.[100] Finally, these participatory interests constitute a right in the strong sense of that term: an interest possessed by an individual that cannot be violated even on a single occasion because of the reasonable or even certain belief that we would all be better off if this interest were sacrificed.[101]

These core participatory interests do not, however, exhaust the democracy-based interests served by the First Amendment. Irrespective of the reason government may have for restricting speech, the audience also has an interest in receiving information it needs to develop informed views on public policy matters.[102] To vindicate this interest, the Court has on occa-

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[98] As the Court explained in *First Nat'l Bank v. Bellotti*, 435 U.S. 765, 791–92 (1978): "[T]he people in our democracy are entrusted with the responsibility for judging and evaluating the relative merits of the conflicting arguments . . . . [I]f there be any danger that the people cannot evaluate the information and arguments . . . , it is a danger contemplated by the Framers of the First Amendment."

[99] It explains, for instance, why defamation of a public official is afforded considerable First Amendment protection, while defamation of a private person on a matter of no public concern is not. *Compare* N.Y. Times v. Sullivan, 376 U.S. 254 (1964), *with* Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749 (1985). It explains why an anti-war protestor has a right to wear a jacket outside a courtroom emblazoned with the message "Fuck the Draft," but why someone inside the courtroom has no right to use vulgar epithets. *Compare* Cohen v. California, 403 U.S. 15, 22 (1971), *with* State v. Lingwall, 637 N.W.2d 311, 315 (Minn. Ct. App. 2001). It explains why a lawyer has a First Amendment right to solicit clients when "seeking to further political and ideological goals" through litigation but not for ordinary economic reasons. *Compare In re* Primus, 436 U.S. 412, 414, 439 (1978), *with* Ohralick v. Ohio State Bar Ass'n, 436 U.S. 447 (1978). And it also explains why, as discussed in detail above, see *supra* notes 67–83 and accompanying text, politically motivated economic boycotts receive rigorous First Amendment protection, while ordinary economic boycotts receive no First Amendment protection whatsoever. *Compare* NAACP v. Claiborne Hardware, 458 U.S. 886 (1982), *with* FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411 (1990).

[100] As discussed above, the right to protest against the United States' involvement in a war is not defeasible even if this protest would harm the war effort. Nor does the First Amendment allow government to excise racist ideas from public discourse even on the quite plausible grounds that such expression leads to discrimination against minorities. *See* WEINSTEIN, *supra* note 8, at 52–59; *see also* Virginia v. Black, 538 U.S. 343 (2003); R.A.V. v. City of St. Paul, 505 U.S. 377 (1992).

[101] *See* RONALD DWORKIN, TAKING RIGHTS SERIOUSLY xi (1977).

[102] This view was famously expounded by Alexander Meiklejohn, who wrote that the First Amendment does not require that "on every occasion, every citizen shall take part in public debate. . . . What is essential is not that everyone shall speak, but that everything worth saying shall be said."

sion extended the First Amendment to speech or activity just because it provides information needed for informed decisionmaking on matters of public concern.[103] This norm cannot, however, be properly characterized as a core First Amendment value. Assuring the flow of information likely to enrich public discourse, apart from any speaker's interest involved in its dissemination, is a concern instrumental to the proper functioning of democracy, not constitutive of it. Thus government interference with information flow (unless instituted for the illegitimate reasons discussed above) would not infringe an individual right in the strong sense of the term. Confirming that laws that impede public access to information needed for democratic decisionmaking do not implicate a core First Amendment right, the Court often defers to legislative judgments that restrictions on information relevant to matters of public concern are justified by some greater social welfare consideration.[104] Thus, the interest in information flow needed

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ALEXANDER MEIKLEJOHN, FREE SPEECH AND ITS RELATION TO SELF-GOVERNMENT 25 (1948). Contrary to Meiklejohn, however, American free speech doctrine is particularly concerned with the opportunity of "every citizen [to] take part in public debate." *See* Robert Post, *Meiklejohn's Mistake: Individual Autonomy and the Reform of Public Discourse*, 64 U. COLO. L. REV. 1109, 1115 (1993) ("Traditional First Amendment doctrine, and a broad spectrum of modern political theories, . . . locat[e] the normative essence of democracy in the opportunity to participate in the formation of the 'will of the community' through 'a running discussion between majority and minority.'" (quoting HANS KELSEN, GENERAL THEORY OF LAW AND STATE 284–88 (Anders Wedberg trans., 1949)). Thus no matter how many times we have all heard the message that Osama bin Laden is evil, I still have a right to voice that view in public discourse.

[103] As discussed above, the Court has created a very narrow right of press access when it is a "necessary precondition" to assuring access to information through which "individual citizen can effectively participate and contribute to our republican system of self government." Globe Newspapers v. Superior Court, 457 U.S. 596, 604 (1982). In addition, in *First National Bank v. Bellotti*, the Court, in a 5-4 decision, invalidated a Massachusetts law strictly limiting political contributions or expenditures by corporations "for the purpose of . . . influencing or affecting the vote on any question submitted to the voters." 435 U.S. 765, 768 (1978) (citation omitted). The restriction was challenged by corporations prevented from spending money to oppose a proposed amendment to the Massachusetts Constitution authorizing a graduated income tax. In responding to the contention that corporations have no First Amendment right to speak, the Court, in an opinion by Justice Powell, responded that "the Constitution often protects interests broader than those of the party seeking their vindication," and noted that that "the First Amendment, in particular, *serves significant societal interests*." *Id.* at 776 (emphasis added); *see also id.* at 783 ("A commercial advertisement is constitutionally protected not so much because it pertains to the seller's business as because it furthers the societal interest in the 'free flow of information.'"). The Court found that the speech the corporation in this case wished to engage in "is the type of speech indispensable to decisionmaking in a democracy." *Id.* at 777 & n.11 (citing, *inter alia*, MEIKLEJOHN, *supra* note 102, at 24–26). Previously, in extending First Amendment protection to commercial speech the Court relied in part on the "general public interest" in the "free flow of commercial information." *See, e.g.*, Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 764 (1976).

[104] *See, e.g.*, McConnell v. FEC, 540 U.S. 93 (2003), which upheld a ban on expenditures by corporations and labor unions for communications that refer to "a clearly identified candidate for Federal office" made 60 days before a general election or 30 days before a primary election. *Id.* at 333–34. Invoking "respect for the legislative judgment that the special characteristics of the corporate structure require particularly careful regulation," *id.* at 205, the Court found that suppression of this speech is justified by the interest in curtailing the "corrosive and distorting effects of immense aggregations of wealth that are accumulated with the help of the corporate form and that have little or no correlation to

for public decisionmaking is properly characterized as an important secondary norm.[105]

2. The Marketplace of Ideas.—Another popular candidate for the fundamental norm underlying the American free speech principle—and one that is particularly relevant to the level of protection afforded social science research—is the search for knowledge and "truth" in the marketplace of ideas. This rationale posits that we will make progress, morally as well as materially, politically as well as scientifically, if all ideas are allowed to compete unimpeded by government regulation. Although this rationale has long informed American free speech doctrine,[106] it is surely not a core value. Otherwise, the First Amendment would not let the government distort the marketplace of ideas through propaganda or maintain a national communications policy that allows media concentration.[107] Another shortcoming with the marketplace of ideas rationale is that the entire premise that a completely unregulated market of ideas will lead either to discovery of truth or to social progress is highly contestable.[108] An even more fundamental flaw with the marketplace of ideas rationale is that it justifies free speech in terms of the good it will produce for society as a whole, not as an individual

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the public's support," as well as in preventing "circumvention of valid contribution limits" imposed on these entities. *Id.* at 205 (citing Austin v. Mich. Chamber of Commerce, 494 U.S. 652, 660 (1990)) (quotation marks and citations omitted); *see also Austin*, 494 U.S. 652 (upholding a state law prohibiting corporations from using corporate treasury funds for expenditures in support of, or in opposition to, any candidate in elections for state office); Seattle Times Co. v. Rhinehart, 467 U.S. 20, 34–35 (1984) (rejecting a First Amendment challenge to a protective order in a civil suit preventing a party from disclosing information of public concern obtained in discovery, the Court cites state interest in preventing potential discovery abuse and in protecting privacy rights of litigants and third parties as justification for restricting the information).

[105] At some extreme point, inadequate access to information can be said to impair the core democratic precept of popular sovereignty, for without a certain quantum of information available to them, in no meaningful sense can the people be said to be governing society. This is true even in the unlikely case that government were to impede the flow of information to this degree for some legitimate reason or even incidentally, not because it mistrusts the people to make wise choices or for any other illegitimate reason. That violation of instrumental norms can, in an extreme case, constitute a breach of core norms reveals that the distinction between the core and the periphery of rights is somewhat artificial. The distinction is, however, nonetheless helpful, perhaps even necessary, for a coherent constitutional rights jurisprudence.

[106] First invoked by John Milton in the seventeenth century, see JOHN MILTON, AREOPAGITICA: FOR THE LIBERTY OF UNLICENSED PRINTING (Precy Lund, Humphries & Co. 1927) (1644), the truth-discovery rationale for free speech was fully developed in the middle of the nineteenth century by John Stuart Mill. *See* JOHN STUART MILL, ON LIBERTY (Edward Alexander ed., 1999) (1859). It was introduced into Supreme Court jurisprudence by Justice Oliver Wendell Holmes, who wrote that "the ultimate good desired is better reached by free trade in ideas" and that "the best test of truth is the power of the thought to get itself accepted in the competition of the market . . . ." Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).

[107] *See* Weinstein, *Database Protection*, *supra* note 66, at 324 & n.7, 344–48.

[108] *See* sources cited in *id*. at 324 n.109.

right.[109] Thus as a prominent theorist has concluded, the "marketplace of ideas theory is fundamentally unsound both normatively and descriptively."[110]

Despite the lip service that the Supreme Court has paid to the marketplace of ideas,[111] if ever squarely presented with the question the Court would, I believe, conclude, for the reasons just mentioned, that speech that promoted only this value is entitled to much less rigorous protection than that accorded the speech by which we govern ourselves. Such a result would be consistent with a recent case that refused to apply any meaningful scrutiny to a copyright law that arguably robbed the pubic domain of important ideas and information.[112] Thus far from a core free speech norm, the marketplace of ideas rationale is at most a peripheral value.

3. Individual Autonomy, Self-Expression and Self-Fulfillment.— Some have argued that the promotion of the cognate norm comprising individual autonomy, self-expression, and self-fulfillment is a core First Amendment value.[113] As a descriptive matter at least, this argument need not long detain us. As a prominent proponent of an autonomy-based free speech jurisprudence has conceded, commitment to the "development of the individual's powers and abilities" or to "the individual's control of his or her own destiny through making life-affecting decisions" is inconsistent with the entire concept of "unprotected speech" such as obscenity and fighting words, not to mention the multitude of financial, commercial, and professional speech that government routinely regulates without any First Amendment hindrance.[114]

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[109] In a technical sense, free speech justified by the marketplace of ideas is an individual right: because it posits that for the benefit to society to occur each person must be able to speak freely, this theory assigns a free speech right to the individual. But this assignment differs from a true individual right which locates the right in the individual not for some strategic reason but out of a basic moral precept about the proper relationship between the individual and the state. Unlike rights grounded in such a basic moral precept, instrumentally-based rights such as those based on a marketplace of ideas theory are vulnerable to being overridden in a specific instance or even extinguished altogether if the utilitarian calculus suggests that society would be better off, either in a particular instance or generally, without this particular right. *See* FREDERICK SCHAUER, FREE SPEECH: A PHILOSOPHICAL INQUIRY 23 (1982) ("If the argument from truth generates a Free Speech Principle, then we [may] justify suppression based on any interest other than the search for truth by weighing the interest in discovering truth against the other interests sought to be protected.").

[110] C. Edwin Baker, *First Amendment Limits on Copyright*, 55 VAND. L. REV. 891, 897 (2002).

[111] *See, e.g.*, Red Lion Broad. v. FCC, 395 U.S. 367, 390 (1969) (stating that "it is the purpose of the First Amendment to preserve an uninhibited marketplace of ideas in which truth will ultimately prevail").

[112] *See* Eldred v. Ashcroft, 537 U.S. 186 (2003).

[113] *See, e.g.*, C. EDWIN BAKER, HUMAN LIBERTY AND FREEDOM OF SPEECH (1989); David Richards, *Free Speech and Obscenity Law: Toward a Moral Theory of Obscenity Law*, 123 U. PA. L. REV. 45 (1974); *cf.* Martin H. Redish, *The Value of Free Speech*, 130 U. PA. L. REV. 591 (1982).

[114] Redish, *supra* note 113, at 593, 626.

There is, however, a more refined version of the autonomy theory that emphasizes the importance of a free flow of ideas and information to facilitate individual as opposed to collective decisionmaking.[115] This view is supported by the Court's decision to extend First Amendment protection to ordinary commercial advertising, in which it noted that, in addition to providing information needed to decide matters of public concern, such speech also aids private economic decisionmaking.[116] How the Court will reconcile protection of commercial speech under this rationale with its adamant refusal since 1937 to directly afford any meaningful protection to private economic decisionmaking under its Fourteenth Amendment substantive due process jurisprudence[117] remains to be seen. Still, the commercial speech cases suggest that the Court might afford similar protection to the dissemination of information that could promote individual decisionmaking, be it economic, recreational, or medical.

C. Determining the Level of First Amendment Scrutiny of IRB Regulations as Applied to Social Science Research

We are now in a position to determine whether the application of IRB regulations to social science research should trigger any First Amendment scrutiny, and if so, how much. What we shall discover is that although social science research typically involves communicative elements not usually found in biomedical research, such as surveys, interviews, and other written and oral communications with subjects, it is not at all obvious why this should matter. Viewed narrowly, these communicative elements would not seem to have any special constitutional significance in themselves but are valuable only as a means towards producing knowledge that will be disseminated to the public. But in that case, social science research would be no different than biomedical research so far as the First Amendment is concerned. If, however, ordinary interview techniques commonly used by social scientists were viewed as part of an important medium of public discourse, then these communications might warrant significant First Amendment protection.

1. Free Speech Values Implicated by IRB Regulation.—If we focus narrowly on the communicative elements of social science research, it would seem that this speech is far afield from the core democratic norm underlying the First Amendment. When, for instance, a psychologist asks

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[115] Such a view is based on a capacious view of constitutionally protected decisional autonomy and as such is in tension with the Court's narrow view of decisional autonomy in its Fourteenth Amendment substantive due process jurisprudence with respect to such crucial matters as the right of terminally ill people to determine the timing of their death. *See* Washington v. Glucksberg, 521 U.S. 702 (1997). For a further discussion of the Court's substantive due process jurisprudence and its reluctance to recognize new fundamental rights, see *infra* notes 220–22 and accompanying text.

[116] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 761 (1976).

[117] *See* SULLIVAN & GUNTHER, *supra* note 39, at 511.

subjects to try to match pictures of dogs to those of their owners to determine if dogs really do resemble their owners,[118] or a linguist records the language of waiters and waitresses,[119] the researcher is by no stretch of the imagination participating in the speech by which we govern ourselves. This is true even when an investigator asks questions in connection with research that is likely to yield information relevant to public decisionmaking, such as what influences teenagers to begin smoking cigarettes. In either situation, the purpose of social scientist's communication with the subjects is to elicit information relevant to the research project, not to try to persuade them about some matter of public concern. Indeed, social scientists usually adopt measures to ensure that they do not influence their subjects towards a particular response.[120]

From this narrow perspective, not only is it inaccurate to view social scientists communicating with their subjects as speakers involved in public discourse, but as the very term "subject" implies, it is incongruous to conceive these subjects as an audience of independent and autonomous citizens involved in democratic self-governance as to whom the First Amendment ordinarily prevents the application of paternalistic measures.[121] Indeed, if the research can have adverse consequences for the participant,[122] subjects of social science research are more properly conceived as "dependent and vulnerable."[123]

Viewed from a wider perspective, however, these communicative elements have greater First Amendment significance. The communication between researcher and subject is an essential component of a larger enterprise which, at minimum, will usually contribute to the discovery of knowledge and can produce information pertinent to both private and public decisionmaking. Indeed, when viewed from this broader perspective, some social scientists may well have undertaken the research with both the hope and desire of discovering information that will persuade people on some matter of public concern.[124] On this view, social science research involves speech intimately connected with the entire gamut of free speech values, including the occasional core interest in democratic participation.

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[118] *See* Michael M. Roy & Nicholas J.S. Christenfeld, Commentary, *Dogs Still Do Resemble Their Owners*, 16 PSYCHOL. SCI. 743 (2005).

[119] *See* Hamburger, *supra* note 2, at 299 n.71 (mentioning linguistic observation of waitstaff as an example of research that might be subject to IRB approval).

[120] *See* 3 ENCYCLOPEDIA OF PSYCHOLOGY 294–95 (Alan E. Kazdin ed., 2000) (discussing the problem of "experimenter expectancy effect" and ways to control it).

[121] *See* Weinstein, *Speech Categorization*, *supra* note 97, at 1103, 1112–13.

[122] *See supra* note 1 and accompanying text; *infra* notes 143–47, 152 and accompanying text.

[123] *See* Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. REV. 1, 4, 23–24, 41 (2000); Weinstein, *Speech Categorization*, *supra* note 97, at 1106.

[124] *See, e.g.*, Brown v. Bd. of Educ., 347 U.S. 483, 494–95 n.11 (1954) (relying on social science research demonstrating detrimental effects of segregation on black children's motivation to learn).

There is, however, a major conceptual problem with this wider perspective. The "expressive elements" of social science research that this argument claims warrant First Amendment scrutiny are *communication with the human subjects*, not the publication of information. But the capacity to produce information relevant to public decisionmaking is by no means confined to social science research. Biomedical research can also produce such information—for example, the studies showing that smoking causes lung cancer. Thus, the communicative elements typically present in social science but ordinarily lacking in biomedical research have no logical bearing on the First Amendment value of information produced by this type of research. Accordingly, with respect to First Amendment values burdened by IRB regulation, social science research seems no different than biomedical research. As demonstrated in Part I of this Article, the connection between biomedical research and eventual publication is insufficient to warrant any First Amendment protection.

It could be argued that social science research is more likely to produce information relevant to public decisionmaking than is biomedical research and is for this reason is more worthy of First Amendment protection. But this may not in fact be true and would in any event be hard to quantify. A lot of biomedical research has implications for public policy decisions, such as studies on the effect of various foods and drugs on public health, discoveries for the control of communicable disease, and investigations into whether certain groups of people are unusually susceptible to various maladies. Conversely, much social science research, such as most linguistic and anthropological research and many psychological studies, have no obvious connection with public decisionmaking. But even if, on the whole, social science research is more likely than biomedical research to produce information relevant to public decsionmaking, the presence of significant communicative elements in typical social science research remains irrelevant to this argument for extending First Amendment protection of social science research.[125]

A better argument for tying communicative elements that are present in some (but not all) social science research to important free speech values is that surveys, questionnaires and interviews used to elicit information from people to be conveyed to the public constitute a medium of communication forming part of the "structural skeleton that is necessary . . . for public dis-

[125] This difference would, of course, be a relevant argument for extending First Amendment protection to social science research under the "necessary condition for speech" theory considered in Part I. As we have seen, however, the Court has tightly confined this protection to conduct closely connected to the core political speech such as expenditures for speech in support of political candidates or access to public proceedings. *See supra* notes 24–31 and accompanying text. Since only a very limited amount of social science research is even arguably so intimately connected to participation in the democratic process, it is highly doubtful that any such difference would lead the Court to extend First Amendment protection to social science research on this theory.

course to serve the constitutional value of democracy."[126] On this view, a social scientist interviewing a "subject" has the same First Amendment value as a journalist interviewing a "source." Since a law requiring journalists to get prior approval from a review board before interviewing a source would undoubtedly be unconstitutional,[127] the argument continues, so would application of IRB regulations to interviews by social scientists.[128] Significantly, however, this theory would not offer protection to other forms of communication between researcher and subject that involved communication other than traditional interviewing techniques such as psychological experiments in which subjects are tested after exposure to various stimuli.[129]

The argument that traditional interviewing techniques such as surveys, questionnaires and oral questions used to elicit information to be disseminated to the public is communication of constitutional significance is a powerful one. Accordingly, funding issues aside,[130] it is possible that the Court would find IRB regulations unconstitutional as applied to research using only traditional interview techniques.[131] Still, there are significant dif-

[126] Post, *supra* note 96, at 1276. I am indebted to Professor Post for suggesting this idea to me.

[127] *See generally* Lovell v. Griffin, 303 U.S. 444, 451 (1938) (stating, in facially invalidating a city ordinance prohibiting the distribution of "literature of any kind" without prior written permission of the City Manager, that the ordinance "strikes at the very foundation of the freedom of the press by subjecting it to license and censorship. The struggle for the freedom of the press was primarily directed against the power of the licensor."); Lakewood v. Plain Dealer Publ'g Co., 486 U.S. 750, 760 (1988) (noting, in facially invalidating a local ordinance allowing newspaper vending racks to be placed on public property only upon receipt of a permit which could be denied if the mayor found that doing so was "necessary and reasonable," that the ordinance was directed "narrowly and specifically at expression or conduct commonly associated with expression: the circulation of newspapers").

[128] I am grateful to Eugene Volokh for suggesting this comparison to me. Technically, research involving "survey procedures" and "interview procedures" is exempt from IRB regulation if the identity of the subjects are not discernable from researcher's records and disclosure of the subjects' responses would not have any adverse consequences for the subjects. *See* 45 C.F.R. § 46.101(b)(1)–(3) (2005). But such research is not truly exempt from IRB review. Although "exempt research" is "free of continued oversight by the IRB," the institution at which the research occurs in the form of "either a designated IRB representative, the entire committee, or some institutional authority, not the researcher" must determine if the project is exempt," a determination that usually requires a "brief review process." *See* National Science Foundation, *supra* note 45; *see also* OFFICE FOR HUMAN RESEARCH PROTECTIONS, DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE ON WRITTEN IRB PROCEDURES (2002), http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd702.htm ("OHRP recommends that institutions adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations.").

[129] *See infra* notes 176–200 and accompanying text.

[130] At this point in the analysis, I am also putting aside the fact that IRB regulations are imposed on employees of the institutions adopting these regulations. This is an important consideration that I will factor into the analysis in connection with the funding discussion in Part IV. Thus the question at this stage of the inquiry is whether government acting not as employer but in its sovereign capacity can constitutionally require social science researchers to obtain prior approval from an IRB before interviewing subjects.

[131] *See In re* Grand Jury Proceedings (Scarce), 5 F.3d 397, 399 (9th Cir. 1993) (assuming without deciding that interviews as part of scholarly research enjoy the same freedom of press protection afforded traditional news gathering).

ferences between social science research and journalism that might lead the Court to take a somewhat different approach towards a law requiring prior approval of social science research using only traditional interviewing techniques. Although there is obviously a considerable area of overlap, social science research and journalism have distinct purposes and perform different societal functions. The primary purpose of research, at least at universities, is to discover knowledge both for its own sake and for the betterment of human kind, not to improve the practice of democracy by supplying the public with information to facilitate the "voting of wise decisions."[132] While some of this knowledge will facilitate public as well as private decisionmaking, much will not. And while academic researchers occasionally engage in research with the specific purpose of producing information to persuade others on matters of public concern, such ideological advocacy is not the primary ethos of academic research and, indeed, can be in tension with the primary academic goal of discovering truth regardless of its political or social implication. In contrast, a primary purpose of journalism is to inform people about matters of public concern[133] and to act as a "watchdog" against governmental abuse and official malfeasance.[134] Similarly, the function of the editorial side of journalism is precisely to influence public opinion.[135]

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[132] ALEXANDER MEIKLEJOHN, POLITICAL FREEDOM: THE CONSTITUTIONAL POWERS OF THE PEOPLE 26 (Oxford Univ. Press 1965) (1948).

[133] *See, e.g.*, First Nat'l Bank v. Bellotti, 435 U.S. 765, 781 (1978) ("The press cases emphasize the special and constitutionally recognized role of that institution in informing and educating the public, offering criticism, and providing a forum for discussion and debate."); Grosjean v. Am. Press Co., 297 U.S. 233, 250 (1936) (observing that "newspapers, magazines, and other journals of the country, it is safe to say, have shed and continue to shed, more light on the public and business affairs of the nation than any other instrumentality of publicity").

[134] *See, e.g.*, Leathers v. Medlock, 499 U.S. 439, 447 (1991) (referring to the press as "a watchdog of government activity"); Minneapolis Star and Tribune Co. v. Minn. Comm'r of Revenue, 460 U.S. 575, 585 (1983) (noting "the basic assumption of our political system that the press will often serve as an important restraint on government"); Smith v. Daily Mail Publ'g Co., 443 U.S. 97, 108–09 (1979) (referring to "press' 'watchdog' role"); Mills v. Alabama, 384 U.S. 214, 219 (1966) ("The press serves and was designed to serve as a powerful antidote to any abuses of power by governmental officials and as a constitutionally chosen means for keeping officials elected by the people responsible to all the people whom they were selected to serve."); *Grosjean*, 297 U.S. at 250 ("[S]ince informed public opinion is the most potent of all restraints upon misgovernment, the suppression or abridgement of the publicity afforded by a free press cannot be regarded otherwise than with grave concern.").

Unlike most academic researchers, journalists see their role as a check on governmental power. *See, e.g.*, Nick Madigan, *Making an Issue of the Media: More and More Politicians Find Attacking Reporters is a Tactic that Pays Off*, BALT. SUN, Aug. 20, 2006, at 1F ("There has long been an assumption that the media 'had a special role to play' in society, given the provision in the Constitution for freedom of the press . . . ." (citing Paul Waldman, a senior fellow at Media Matters for America)); Nicholas Kristof, *Don't Turn Us Into Poodles: What's Worse Than a Press 'Out of Control'? One Under Control*, PITTSBURGH POST-GAZETTE, July 7, 2006, at B7 (arguing that with respect to coverage of recent Presidential decisions the media has "failed in our watchdog role, and we failed our country").

[135] Some have urged that the constitutional protection the crucial democratic function played by journalism should be grounded not in the free speech clause but in the free press clause of the First

This essential difference between social science research and journalism is reflected in the publications through which these two professions communicate with the public—scholarly journals and academic books versus newspapers and magazines. Scholarly publications are usually aimed at a narrow, specialized audience and address people in their professional capacity; journalistic media, in contrast, are typically aimed at a more general audience, often addressing people in their capacity as citizens (as well as consumers). Moreover, not only do general circulation newspapers and magazines usually contain an editorial page in which the publisher and editors try to persuade people on matters of public concern, these publications also often have an opinion page in which members of the public are invited to do the same. In contrast, while some scholarly publications publish editorials and even more commonly letters from scholars in response to an article or some academic issue, these publications do not generally solicit the views of the general public. Accordingly, although scholarly journals and books, on the one hand, and newspapers and magazines, on the other, both form part of the "structural skeleton that is necessary for public discourse to serve the constitutional value of democracy," it is the newspaper and magazines that form the "backbone" of this structure. Scholarly publications, in contrast, contribute less central support for the structure (a "shin bone" perhaps, to continue Post's orthopedic metaphor).

The Court might therefore take a more refined approach to a law that imposed IRB regulations directly upon social scientists at research institutions than it would to similar restrictions imposed on journalists. Borrowing a page from its defamation jurisprudence,[136] the Court might hold that to the extent the interviews related to matters of public concern such as attitudes towards homosexuality, abortion, or the war in Iraq, the regulations could not be applied. With respect to interviews on subjects not of public concern, such as the language used by waiters and waitresses or whether people can match dogs to their owners, the Court might well apply a lesser degree of scrutiny. This distinction would reflect the more important role played by the press in our democracy. It would also take account of the related fact that unlike the typical journalistic interview or survey, many so-

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Amendment. *See, e.g.*, Baker, *supra* note 110, at 919–22; Potter Stewart, *"Or of the Press,"* 26 HASTINGS L.J. 631 (1975). But whatever its source, the protection provided to the press is generally no greater than the protection provided to an individual engaging as a speaker in public discourse. This parity of protection obviates the need to decide if the instrument of communication utilized by the speaker constitutes "the press" for purposes of the First Amendment.

[136] Under this jurisprudence, defamatory statements about the official duties of public officials are highly protected; defamatory statements about private individuals on matters of public concern receive more modest protection; while defamatory remarks about a private person can be regulated by statute or common law with no interference from the First Amendment. *See* Phila. Newspapers, Inc. v. Hepps, 475 U.S. 767, 775 (1986).

cial science interviews and surveys will not contribute to democratic self-governance.[137]

It is true that avoiding an overly-refined doctrine that is difficult to administer[138] argues for deeming all interviewing techniques directed towards producing public information a unified medium warranting the same high level of First Amendment protection. Still, the lesser contribution that social science interviews generally make to the "constitutional value of democracy"[139] suggests that regulations that burden these communications should trigger something less than the exacting scrutiny that would be applied if IRB regulations were applied to journalists' communication with their sources.[140]

2. A Values-Driven Application of Free Speech Doctrine to IRB Regulation of Social Science Research.—To see how such a values-driven approach to the free speech issues might play out in actual practice, let's consider four scenarios, two involving content-neutral applications of IRB regulations and two that are content based.

a. Content-neutral applications.—Suppose that Professor Parsons, a sociologist whose research consists exclusively of surveying people about their attitudes on various subjects, files a lawsuit arguing that the very notion of having to get permission before he interviews subjects is in prin-

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[137] Of course not all journalistic interviews contribute to democratic self-governance, but the fact that most do and the critical importance of this medium to democratic self-governance argue against any such refined approach for the press. Because of the important check the press plays in our constitutional system against governmental malfeasance and abuse, it is much more likely that even facially-neutral regulations of such an essential journalistic practice as interviewing sources of information might be motivated by a desire to squelch this important "watch dog" function. In contrast, there is much less reason to be suspicious of such an illegitimate government purpose in applying IRB regulations to social scientists' interviews with their subjects.

[138] The distinction between matters of public and private concern, although no stranger to the law, is not self-defining and might in close cases be difficult to administer.

[139] Post, *supra* note 96, at 1276.

[140] Indeed, gradations among highly protected media already seem to exist. For instance, cable broadcasting is more highly protected than over-the-air broadcasting. *Compare* FCC v. Pacifica Found., 438 U.S. 726 (1978) (upholding against a First Amendment challenge to federal law giving the FCC authority to prohibit radio and over-the-air television broadcasts of sexually explicit or profane material at times when children are likely to be in the audience), *with* Playboy Entm't Group, Inc. v. United States, 529 U.S. 803 (invalidating similar law as applied to cable broadcasting). In addition, the Court has upheld licensing systems for film that it would not allow to be applied to the print medium. *See* Times Film Corp. v. Chicago, 365 U.S. 43 (1961). Similarly, although the Court upheld a regulation requiring over-the-air broadcasters to provide free time to individuals subject to personal attack on the air, the Court held unconstitutional a state law requiring newspapers to allow political candidates to reply free of charge to criticism of them by the newspaper. *Compare* Red Lion Broad. Co. v. FCC, 395 U.S. 367 (1969), *with* Miami Herald Pub. Co. v. Tornillo, 418 U.S. 241 (1974). And the fierce scrutiny the Court applied to the Communications Decency Act suggests that the Internet may be the most highly protected medium of all. *See* Reno v. ACLU, 521 U.S. 844 (1997).

ciple an unconstitutional burden on his right of free speech.[141] For the reasons discussed above, unless the constitutional defect is avoided by the fact that the restrictions are imposed as a funding condition rather than by force of law, the Court might agree with this claim, though in my view it is more likely that it would do so only to the extent that the interviews were on matters of pubic concern.[142] Let's assume, then, that at most the Court would find the prior review requirement in principle inconsistent with the First Amendment only as applied to research involving interviews or surveys on matters of public concern. The question then remains as to the compatibility of such prior review as applied to social science research that has no such obvious connection with democratic self-governance. As to this type of research, the Court would likely apply the *O'Brien* test and uphold the prior review requirement.

On its face, the requirement of prior review is speech neutral, covering research both with and without any significant communicative elements. Furthermore, as a formal matter at least, its application to social science research is also best characterized as speech-neutral. Many of the criteria for IRB approval—such as equitable selection of the subjects,[143] consideration of "the special problems of research involving vulnerable populations,"[144] and informed consent[145]—are not speech related.[146] True, this review also involves a general assessment of the risk of harm, which in the case of social science research will often involve harm flowing from the communicative elements of the study rather than, say, the temperature in the room. But such concern with the communicative elements of the research is not inevitable. Accordingly, even as applied to social science research, the prior re-

[141] Such a suit would in effect be a hybrid of a facial and an as-applied attack in that it would amount to a *facial challenge* to *the application* of the entire IRB system to all social science research using traditional interview techniques.

[142] Such an application of IRB regulations might nonetheless be constitutional if imposed on researchers not by government acting in its sovereign capacity, as we are assuming at this stage of the analysis, but by a state university that had adopted such a policy on its own accord. *See* Garcetti v. Ceballos, 126 S. Ct. 1951, 1958 (2006) ("The government as employer indeed has far broader powers than does the government as sovereign." (quoting Waters v. Churchill, 511 U.S. 661, 671 (1994) (plurality opinion))). For a further discussion of this issue, see *infra* notes 300–02 and accompanying text.

[143] *See* 45 C.F.R. § 46.111(a)(3) (2005); *see also* National Science Foundation, *supra* note 45 ("The principle of justice concerns the distribution of the burden of research and the reaping of possible benefits.").

[144] 45 C.F.R. § 46.111(a)(3).

[145] *See* 45 C.F.R. §46.111(a)(4)–(5).

[146] Another key requirement—protecting of the privacy of the subjects and maintaining the confidentiality of the data, 45 C.F.R. §46.111(a)(7)—is arguably speech related in that breaches of privacy and confidentiality will almost always occur through communication of information. But communicative activity of this sort is different from the communicative elements that distinguish social science from biomedical studies and thus arguably endow social science research with First Amendment importance. In contrast, a requirement that researchers, be they social scientists or biomedical investigators, respect the privacy of subjects and maintain the confidentiality of the data, would not ordinarily raise any First Amendment problem.

view requirement is best conceptualized as a mechanism that seeks to identify and mitigate *all* risks to subjects presented by the research, irrespective of whether they arise from the expressive or nonexpressive elements of the research. It is only after this review process identifies a speech-related harm and some modification is requested to reduce or eliminate this harm that the application of the IRB process becomes both speech related and content based.[147] Thus the requirement of prior review will most likely be considered a speech neutral regulation imposing an incidental burden on the communicative elements of social science research.

When the Court applies First Amendment scrutiny to a regulation of conduct incidentally burdening expression, it usually applies the intermediate scrutiny imposed by the *O'Brien* test.[148] Under *O'Brien*,

> a government regulation [incidentally burdening speech] is sufficiently justified if it is [1] within the constitutional power of the Government; [2] if it furthers an important or substantial governmental interest; [3] if the governmental interest is unrelated to the suppression of free expression; and [4] if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest.[149]

Because the first prong of the *O'Brien* test is not part of a free speech analysis[150] and the third inquires whether the application is speech neutral,[151] prongs three and four constitute the actual First Amendment scrutiny imposed by the *O'Brien* test on speech-neutral burdens on the expressive elements of conduct. With regard to the second prong, there can be no doubt

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[147] *See infra* notes 172–207 and accompanying text.

[148] United States v. O'Brien, 391 U.S. 367 (1968); *see supra* notes 51–52 and accompanying text. As discussed above, *supra* notes 54–60, 82–83, 125 and accompanying text, it is possible that the Court would refuse to subject this application of the IRB regulation to any First Amendment scrutiny. Because, however, traditional interviewing methods are arguably part of a medium essential to democratic self-governance, it would be a mistake for the Court to take this approach.

[149] 391 U.S. at 377.

[150] With respect to federal provisions, the requirement that the regulations be "within the Constitutional power of government" raises not a First Amendment problem but the federalism question of whether the regulation is within the scope of the federal government's delegated power. Here this requirement would inquire whether the federal government's conditioning its grants to research institutions on the institution's agreement to implement IRB is within Congress's spending power. *See infra* note 253. It is not at all clear that this requirement, which was developed in a case reviewing a federal law, has any applicability to state regulations. Unlike the federal government, states have general power. To the extent that this requirement merely asks whether the state interest is legitimate, that would be subsumed by the second requirement that the regulation further an "important or substantial" government interest. Nonetheless, although it would seem otiose to have done so, a plurality of Court applied the first requirement to a city ordinance in *City of Erie v. Pap's A.M.*, 529 U.S. 277, 296 (2000).

[151] *See* Dorf, *supra* note 61, at 1202 ("Prong three [of the *O'Brien* test] merely restates the proposition that the challenged regulation must be content-neutral—which is a precondition for the application of the test in the first instance."). Of course, as Eugene Volokh emphasizes, a regulation of conduct can be speech-neutral on its face but content-based as applied to an expressive activity. *See* Volokh, *supra* note 66, at 1284. As discussed *supra* notes 143–47 and accompanying text, the prior approval requirement simpliciter is best conceptualized as speech-neutral.

that reducing the various risks of harm that social science research poses to human subjects is an "important" or "substantial" interest. Nor can it be doubted that prior approval to identify these risks furthers this interest.

It could be argued that whatever might be said of the use of human subjects in biomedical research, and even some social science research such as Milgram's famous experiment,[152] research such as that Professor Parsons wants to conduct using exclusively traditional interview methods will rarely inflict such harm. It is true that the risk of harm to subjects of social science research is both far less likely and much less serious than those involved in biomedical research. But as the *Institutional Review Board Guidebook* points out, mere questioning on "sensitive subjects such as drug use, sexual preference, selfishness, and violence" can cause "[s]tress and feelings of guilt or embarrassment."[153] And as mentioned above,[154] there are other risks of harm that might be reduced by requiring prior IRB approval of the use of human subjects in even this type of social science research, including assuring that the subjects have given informed consent, that their privacy will be protected, that vulnerable populations are not exploited, or that members of minority groups are not excluded from any benefits appurtenant to being a research subject.

Even a slight or speculative reduction of any of these risks that would be accomplished by IRB prior review would easily meet *O'Brien's* second requirement, as *City of Erie v. Pap's A.M.*[155] demonstrates. In that case, a city justified its application of a ban on public nudity to erotic nude dancing as a means of combating "the negative secondary effects" such as violence, sexual harassment, public intoxication, prostitution, and the spread of sexu-

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[152] *See* Stanley Milgram, *Behavioral Study of Obedience*, 67 J. ABNORMAL & SOC. PSYCHOL. 371 (1963). In an experiment investigating the conflict between personal conscience and obedience to authority, subjects were told that they were participating in a study that tested the effects of punishment on learning behavior. Acting as "teachers," subjects administered an electric shock to the "learner" (a confederate of the experimenter) whenever a question was answered incorrectly. As the intensity of the shocks increased, the "learner" complained of severe pain. When the subjects expressed concern for the "learner," the experimenter strongly urged them to continue with the experiment. Results showed that although subjects were experiencing severe stress over their actions, they continued to obey the experimenter. For a criticism of the ethics of this experiment, see Diana Baumrind, *Some Thoughts on the Ethics of Research: After Reading Milgram's "Behavioral Study of Obedience*," 19 AM. PSYCHOLOGIST 421 (1964).

[153] OFFICE FOR PROTECTION FROM RESEARCH RISKS, DEP'T OF HEALTH AND HUMAN SERVS., PROTECTING HUMAN RESEARCH SUBJECTS: INSTITUTIONAL REVIEW BOARD GUIDEBOOK 3-3 (1993) [hereinafter INSTITUTIONAL REVIEW BOARD GUIDEBOOK]. *See also* National Science Foundation, *supra* note 45 (noting ("[e]motional or psychological harm . . . when a research interaction cause[s] upset, or worry about breach of confidentiality as a type of harm that can arise from social science research"). As discussed *infra* text accompanying notes 172–175, 203–207, if an IRB rejected or required modification of a study in order to prevent or mitigate stress and feelings of guilt or embarrassment arising from questions directed to the subjects, the application of the IRB regulation would be considered content based, therefore requiring a different analysis.

[154] *See supra* text accompanying notes 143–146.

[155] 529 U.S. 277 (2000).

ally transmitted diseases purportedly associated with nude dancing establishments.[156] Writing for a plurality of the Court, Justice Sandra Day O'Connor conceded that "requiring dancers to wear pasties and G-strings may not greatly reduce these secondary effects."[157] In finding that *O'Brien's* second prong was nevertheless fulfilled, Justice O'Connor emphasized that this condition requires only that the regulation "further" the asserted interest.[158] Furthermore, in holding that it was not necessary for the city to conduct a study showing that erotic nude dancing caused these effects, but could rely on findings of other jurisdictions, O'Connor explained that "the government generally has a freer hand in restricting expressive conduct than it has in restricting the written or spoken word."[159]

As evidence of the "leeway" that the government has under the second *O'Brien* prong, Justice O'Connor noted that in *O'Brien* itself, the Court "did not require evidence that the integrity of the Selective Service System would be jeopardized by the knowing destruction or mutilation of draft cards. . . . [Rather], the Court permitted Congress to take official notice, as it were, that draft card destruction would jeopardize the system."[160] Under this lax standard, requiring that investigators wishing to use human subjects in their research obtain prior IRB approval obviously "furthers" the important interest of protecting these subjects from various risks of harm.

If read literally, the fourth *O'Brien* requirement that "the incidental restriction on alleged First Amendment freedoms is no greater than is essential" to the furtherance of the government's interest would impose a heavy burden on the government. With respect to IRB regulations, for instance, it certainly could be argued that whatever might be the case with respect to biomedical research, harm to human subjects arising from interviews or surveys is so infrequent and usually so minor that the complex machinery of IRB regulation, including the requirement of obtaining prior approval, imposes a burden on the expressive elements typical of such research that is far greater than essential to avoid these harms. Less speech intrusive measures that might be nearly as effective as prior review might include requirements that the researchers abide by all ethical precepts of their discipline, and that adequate avenues of relief be available to any subject who is injured by the experiments. The fourth prong of the *O'Brien* test, however, does not mean what it says and, in fact, imposes almost no burden of justification on the government. As the Court explained in *United States v. Albertini*, speech neutral regulations that incidentally burden expression are not invalid "simply because there is some imaginable alternative that

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[156] *Id*. at 291.

[157] *Id*. at 301.

[158] *Id*.

[159] *Id*. at 299 (quoting Texas v. Johnson, 491 U.S. 397, 406 (1989)) (quotation marks omitted).

[160] *Id*. at 298–99.

might be less burdensome on speech."[161] Rather, such a restriction is "no greater than is essential" and therefore is permissible under *O'Brien*, "*so long as the neutral regulation promotes a substantial government interest that would be achieved less effectively absent the regulation.*"[162]

Given the laxity of this standard,[163] it is doubtful that application of IRB review even to research involving only traditional interview techniques would offend the fourth *O'Brien* prong.[164] Although the need for prior review as a means of protecting human subjects of social science research from harm may not be great, it is certainly not gratuitous.[165] So long as researchers are able to conduct interviews on matters of public concern free of IRB review, the democratic function served by this medium will not be greatly impaired.

To summarize: application of the IRB prior approval requirement to research involving only interviews and surveys arguably unduly burdens a medium crucial to democratic self-governance and thus, funding issues aside, might be held inconsistent with the First Amendment, especially with

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[161] 472 U.S. 675, 689 (1985).

[162] *Id.* (emphasis added). Subsequent cases have followed *Albertini*'s interpretation of the fourth *O'Brien* requirement. *See* Rumsfeld v. Forum for Academic & Institutional Rights, Inc., 126 S. Ct. 1297, 1311 (2006); City of Erie v. Pap's A.M., 529 U.S. 277, 301–02 (2000); Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 299 (1984). As John Hart Ely has written, this standard forbids only a "gratuitous inhibition of expression." John H. Ely, *Flag Desecration: A Case Study in the Roles of Categorization and Balancing in First Amendment Analysis*, 88 HARV. L. REV. 1482, 1484–85 (1975).

[163] *See infra* note 165.

[164] This would be true even if research involving ordinary interviewing methods were subject to the full rigors of the IRB requirements, rather than being "exempt" and thus needing only initial approval. *See supra* note 128. But since this "exemption" has already lessened the burden, any claim that the fourth prong is violated becomes even less tenable.

[165] Demonstrating just how toothless the second and fourth prongs of the *O'Brien* test are, the Supreme Court has never found a regulation to have failed either of these prongs. *See* Barnes v. Glen Theatre, Inc., 501 U.S. 560, 577 (1991) (Scalia , J., concurring) (observing that "[w]e have never invalidated the application of a general law simply because the conduct that it reached was being engaged in for expressive purposes and the government could not demonstrate a sufficiently important state interest"). At the Supreme Court level at least, the only meaningful part of the *O'Brien* test has been its crucial third prong, which tests whether the proffered justification really is speech neutral. *See id*. at 578 ("All our holdings (though admittedly not some of our discussion) support the conclusion that 'the only First Amendment analysis applicable to laws [of general applicability] is the threshold inquiry of whether the purpose of the law is to suppress communication. If not, that is the end of the matter so far as First Amendment guarantees are concerned . . . .'" (quoting Cmty. for Creative Non-Violence v. Watt, 703 F.2d 586, 623 (D.C. Cir. 1983) (en banc) (Scalia, J., dissenting))). In cases other than ones dealing with incidental burdens on expression imposed by laws of general applicability, the Court has sometimes applied a more searching version of the *O'Brien* test. *See, e.g.*, Turner Broad., Inc. v. FCC, 512 U.S. 622 (1994) (reviewing federal law mandating that cable operators allocate a portion of their channels to local broadcasters). Although subjecting the law to serious scrutiny and remanding the case for further factual findings, *see* Weinstein, *Database Protection*, *supra* note 66, at 335, the Court in a 5-4 decision ultimately sustained the regulation. Turner Broad., Inc. v. FCC, 520 U.S. 180 (1997). Given the importance of interviewing as a medium of democratic participation, it is possible that the Court would similarly apply a somewhat elevated level of *O'Brien* scrutiny even to interviews not involving matters of public concern.

regard to research that is likely to produce information on matters of public concern. But if the Court does not consider social science interviews and surveys to be part of this highly protected medium, it is likely to apply *O'Brien* and uphold the requirement.

Let us next consider a narrower challenge to a content-neutral application of these regulations. Suppose that an anthropologist, Dr. Mead, wants to study kinship in a highly patriarchal society. She knows, though, that if she obtains the consent of women she wants to interview rather than seeking permission to interview them from their fathers and husbands, as well as from the village headman, she will not be welcome in the village and might even cause any woman who cooperates with her to be chastised or even beaten. She explains this to the IRB and asks for a waiver of the requirement that she obtain written consent from the subjects of the research,[166] assuring the IRB that she will inform the women she wants to interview of all the possible risks and obtain their tacit consent before proceeding further. The IRB refuses to grant the exemption, explaining that granting an exemption in this case would "set a bad precedent" and therefore declines to approve the project as proposed. After further requests for an exemption are unavailing, Mead sues the IRB in federal district court seeking a declaration that the requirement of written informed consent is unconstitutional as applied to this research project.

Since the study of kinship in a remote country does not involve interviews on a matter of public concern, it is unlikely that the court would find this restriction in principle inconsistent with the First Amendment, but would probably apply the *O'Brien* standard. Unlike in the previous example, however, it could be strongly argued that neither the second nor the fourth *O'Brien* prong is met in this case: The second prong is not fulfilled because insisting on the written informed consent will actually result in more harm to the subjects than dispensing with it, and therefore will not further the government's interest in protecting subjects from the risk of harm. Similarly, the fourth prong is not satisfied because the government's interest in preventing harm to human subjects would be more effectively achieved without the written informed consent. Accordingly, the argument

[166] An IRB may waive the requirement that informed consent be documented by a written consent form if "the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context." 45 C.F.R. § 46.117(c)(2) (2005). In addition, § 46.116(d) authorizes the IRB to waive or alter the informed consent requirement in appropriate circumstances. *See also* National Science Foundation, *supra* note 45 ("The cultural norms and life-styles of subjects should be considered in deciding how to approach informed consent. Issues such as whether to . . . deal with subjects individually or in groups, seek the consent of gatekeepers or superiors in lieu or in addition to the individual subjects' consent . . . should be dictated by the culture and context of the research and the level of risk. . . . Persons should be treated respectfully in accordance with their culture and circumstances."). Moreover, in this scenario it is arguable that obtaining the informed consent of the village headman, fathers, and husbands complies with the general requirement that the researcher obtain the informed consent of the subject "or the subject's legally authorized representative." 45 C.F.R. § 46.116 (2005).

concludes, incidental though it may be, the burden placed on the researcher's right to communicate with these women by this application of the informed consent requirement is (funding issues aside) unconstitutional.

The IRB would likely respond by quoting *Albertini*'s instruction that "[r]egulations that burden speech incidentally . . . must be evaluated in terms of their general effect," not in terms of whether allowing "an exception in the particular case will . . . threaten important government interests."[167] Dr. Mead would doubtless reply that while every application of regulation need not advance the governmental interest, this application would actually undermine that interest. The government would likely rejoin by emphasizing that the "validity of such regulations does not turn on a judge's agreement with the responsible decisionmaker concerning the most appropriate method for promoting significant government interests."[168]

Because "analogy without theory is blind,"[169] the usual methodology of case matching and quotation of dicta can provide only limited guidance in a novel case like this. Once again the answer will depend on what free speech values are implicated by the regulation. As discussed above, although interviewing is arguably a medium essential to democratic self-governance, the effectiveness of this medium will not likely be impaired by application of IRB regulations to academic interviews on matters not of public concern. Also arguing against granting relief in this case is that doing so would invite numerous other attacks on IRB regulations, many of which will not be as meritorious, but which lower courts might nonetheless sustain, thereby creating a "gaping hole in the fabric of those laws."[170] But if the Court were ever to invalidate a speech restriction under *O'Brien*, it would likely do so in a case such as this where the government's argument for application of the restriction is not only weak but arguably perverse.[171]

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[167] United States v. Albertini, 472 U.S. 675, 688–89 (1985); *see also* FTC v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411, 430 (1990); Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 296–297 (1984) (holding that "the validity of this regulation need not be judged solely by reference to the demonstration at hand").

[168] *Albertini*, 472 U.S. at 689.

[169] Ronald Dworkin, *In Praise of Theory*, 29 ARIZ. ST. L.J. 353, 371 (1997).

[170] *Trial Lawyers Ass'n*, 493 U.S. at 431–32.

[171] Indeed, most problematic IRB decisions seem to be a product not of the IRB regulations themselves but rather of mis- or over-application of these regulations. *See* Jerry Menikoff, *Where's the Law? Uncovering the Truth About IRBs and Censorship*, 101 NW. U. L. REV. 791 (2007) ("To the extent that social and behavioral scientists find themselves facing inappropriate burdens in conducting their research, the most likely cause of that problem is their institution's flawed operations."); Posting of Jeffrey Cohen to HRPP Blog, http://hrpp.blogspot.com/2006/03/mission-creep.html (Mar. 4, 2006, 10:14 EST) (explaining that the "horror stories" about application of IRB review to social science research result because the IRBs "don't understand social and behavioral research[,] don't know how to use or are afraid to use the flexibility in the regulations, and . . . don't pay sufficient attention to the efficiency of their procedures").

b. Content-based applications.—Content-based regulations of speech are generally more problematic from a First Amendment perspective than are content-neutral ones.[172] As applied to social science research, the rule requiring that the "[r]isks to subjects [be] minimized"[173] and "reasonable in relation to anticipated benefits" are content based to the extent that these "risks" flow from the communicative elements of the research,[174] which will usually be the case. The official guidebook to interpreting IRB regulations warns, for instance, of the "stress" and "feelings of guilt or embarrassment" arising "from thinking or talking about one's own behavior or attitudes on sensitive subjects, such as drug use, sexual preference, selfishness, and violence."[175] Unlike the harm of subjecting people to any risk without their informed consent, or from bodily injury caused by invasive procedures or ingesting toxic substances, harms arising from questions asking subjects to think or talk about their behavior is a direct result of the "communicative elements" of the research. And other types of harm might flow from the communicative impact of research that exposes subject to various stimuli.

Suppose a psychologist, Professor Winston, wants to determine whether images in the media of people smoking actually influence people to smoke. He therefore proposes to show a group of undergraduates movies that portray smoking as glamorous and then to test for effects of this exposure. To minimize "experimenter expectancy effect,"[176] Winston also proposes to disguise the purpose of the experiment by telling the subjects that they are rating movies for a university film program. The subjects will then be given a personality test as part of a large psychology lecture class in which they are all enrolled, with questions embedded in it to determine

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[172] Whether a regulation is content neutral or content based is often key to determining its validity under the First Amendment. *See* WEINSTEIN, *supra* note 8, at 35–38. Indeed, content-based regulations of public discourse are virtually per se impermissible. *See id*. at 35; *see also supra* notes 92–93, 98, 100–01 and accompanying text. Though government generally has far greater leeway to regulate the content of speech other than through public discourse, *see* WEINSTEIN, *supra* note 8, the distinction between content-neutral and content-based regulations remains significant. Even with respect to speech other than that by which we govern ourselves, when government regulates expression because of its communicative impact rather than for some content-neutral purpose, there is a greater likelihood that it is trying to suppress an unpopular idea. But this does not mean that content-based regulation of speech other than public discourse is unconstitutional or even presumptively so. Indeed, as we shall see, some content-based IRB regulations of social science research are no more problematic than content-neutral ones. *See infra* notes 198–200 and accompanying text. Others, however, are more suspect. *See infra* notes 201–07 and accompanying text.

[173] 45 C.F.R. § 46.111(a)(1)–(2) (2005).

[174] *See* Turner Broad. Sys., Inc. v. FCC, 512 U.S. 622, 642–43 (1994) (stating that a content-neutral law is one that is justified without reference to the content of the regulated speech); Volokh, *supra* note 66, at 1284 (explaining that a facially content-neutral or speech-neutral law is content based "as applied" when "speech triggers the law because of the harms that may flow from what the speech says").

[175] INSTITUTIONAL REVIEW BOARD GUIDEBOOK, *supra* note 153, at 3-3.

[176] *See supra* note 120 and accompanying text.

whether watching these films influenced their judgment about the relative costs and benefits of smoking.[177]

The IRB refuses to approve this study, giving the following two reasons for the denial: First, it fears that exposing students to films showing smoking in a positive light will in fact make it more likely that they will begin smoking. In addition, the IRB objects to deceiving the subjects about the purpose of the study.[178] In response, Professor Winston offers to make sure that all of the students exposed to the favorable depictions of smoking are "deconditioned," but insists that the deception is necessary to obtain accurate results. The IRB responds that the psychologist cannot guarantee that the students in the target group will agree to such deconditioning, which in any event might not be effective, and that the harm caused by the deception is not, in its view, justified by the benefit of the research.

Having exhausted all other avenues of relief, Professor Winston sues the IRB in federal district court. To what level of First Amendment scrutiny would such content-based applications be subject? Unlike the two previous scenarios, the communicative aspects of this experiment do not involve ordinary interview techniques arguably forming a part of an essential medium of public discourse. Accordingly, the application of IRB regulation to this experiment, if it triggers any First Amendment scrutiny at all, would be evaluated under the *O'Brien* test. As a content-based application, however, it would fail the third prong of *O'Brien*, which requires the regulation to be unrelated to "the suppression of expression."[179] The analysis is therefore pushed "outside of *O'Brien*'s test altogether."[180] This means that the regulation should be treated as a direct, content-based regulation of speech, subject to whatever level of scrutiny such a speech regulation would

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[177] This scenario is based on an ingenious experiment by Malamuth and Check which employed similar techniques to assess the effects of viewing pornography. *See* Neil M. Malamuth & James V.P. Check, *The Effects of Mass Media Exposure on Acceptance of Violence Against Women: A Field Experiment*, 15 J. RES. IN PERSONALITY 436 (1981).

[178] *See* National Science Foundation, *supra* note 45 ("Deception poses ethical problems and should be dealt with by weighing the benefits of the research against the harm (if any) of the deception. Aside from any potential harm to participants, deception can also harm the institution by building the perception among potential subjects that 'researchers are liars.'"). Since deception would vitiate informed consent, a researcher wanting to deceive subjects about the purpose of a study would need a partial waiver of this requirement. *Id*.; *see also* 45 C.F.R. § 46.116(d) (2005).

[179] United States v. O'Brien, 391 U.S. 367, 377 (1968).

[180] Texas v. Johnson, 491 U.S. 397, 410 (1989). By "outside" of the *O'Brie*n test, the Court meant because the restriction was justified by a speech related interest, the test developed for incidental burdens on speech imposed by laws aimed at conduct was no longer applicable. Thus, rather than apply "the less stringent" scrutiny imposed by the remainder of the *O'Brien* test, *id*. at 403, the Court applied the strict scrutiny appropriate to content-based regulations of political expression in a pubic forum at issue in that case. *Id*. at 412.

trigger.[181] The key inquiry in this case thus reduces to the following question: What level of First Amendment scrutiny would be applicable to a law that prohibited researchers from making any deceptive statement to research subjects concerning the purpose of the research and further prohibited exposing subject to material that the researcher has reason to believe might influence them to engage in an activity that might endanger their health?

Under a commonly held but seriously mistaken view, this regulation would be subject to strict scrutiny because it is a content-based speech regulation.[182] Aptly dubbed the "All Inclusive Approach,"[183] this view posits that "all speech receives First Amendment protection unless it falls with[in] certain narrow categories of expression . . . such as incitement to illegal conduct, intentional libel, obscenity, child pornography, fighting words and true threats." Thus unless the speech falls into one of these forlorn categories, any law that regulates speech because of its content will be subject to strict scrutiny.[184]

Although the All Inclusive Approach may be a useful fiction and even a workable rule for routine cases,[185] speech is much too ubiquitous an activity with far too many real world consequences for there to actually be any such rule.[186] One need only consider the large range of speech regulated by securities, antitrust, labor, copyright, food and drug, and health and safety laws, together with the array of speech regulated by the common law of

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[181] *See* Schauer, *Cuban Cigars*, *supra* note 62, at 785 n.24 (noting that "a variety of different" levels of scrutiny may be triggered, "depending on the particular nature of the communicative impact and the nature of the government interests"). Indeed, because IRB regulations are rules of general applicability, it is not certain their application to social science will trigger the *O'Brien* test or any level of First Amendment scrutiny, even if the application is content based. *See* FTC. v. Superior Court Trial Lawyers Ass'n, 493 U.S. 411, 430 (1990); *see also supra* notes 73–83 and accompanying text.

[182] Indeed, because it does not forbid exposing subjects to material that might influence them to engage in activities that will promote their health, the regulation is arguably viewpoint based.

[183] McDonald, *supra* note 20, at 1009.

[184] *Id.* For other statements of the All Inclusive Approach or variations on it, see, for example, JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW § 16.47, at 1226 (6th ed. 2000) ("A content-based restriction of [speech] is valid only if it fits within a category of speech that the First Amendment does not protect, for example, obscenity."); EUGENE VOLOKH, THE FIRST AMENDMENT: PROBLEMS, CASES, AND POLICY ARGUMENTS 2 (2001) (stating that besides the traditional "exceptions," the settings in which government may regulate the content of speech are confined to those in which it is acting as proprietor or educator, rather than a sovereign).

[185] In routine free speech cases, it is arguably preferable if judges do not appeal to first principles but instead apply a simple rule such as provided by the All Inclusive Approach. Not only does such a bright line test give ordinary citizens a fairly good idea of what they can say or publish without fear of prosecution, it also prevents prosecutors, judges and juries from smuggling their antipathy towards unpopular ideas or groups into the analysis.

[186] *See* Garcetti v. Ceballos, 126 S. Ct. 1951, 1973 (2006) (Breyer, J., dissenting) ("Because virtually all human interaction takes place through speech, the First Amendment cannot offer all speech the same degree of protection. Rather, judges must apply different protective presumptions in different contexts, scrutinizing government's speech-related restrictions differently depending upon the general category of activity."); WEINSTEIN, *supra* note 8, at 40–41.

contract, negligence and fraud, all without a hint of interference from the First Amendment, to quickly realize that there is a multitude of "exceptions" beyond the few recognized by the All Inclusive Approach.[187] Thus, a more accurate snapshot of First Amendment protection is the photonegative of All Inclusive approach: It is the highly protected speech that is the exception, with most other speech regulable with no discernable constraint from the First Amendment.[188]

Accordingly, in cases that are either novel or hard, such as those presented by content-based applications of IRB regulations, the All Inclusive Approach is likely to grossly overprotect speech at the expense of legitimate regulatory interests.[189] In such cases there is no alternative but to consult the values underlying free speech doctrine to determine the level of protection needed to promote these norms. We have already discussed how the burdens placed on the expressive elements of social science research by content-neutral applications of IRB regulations will not ordinarily interfere with the core free speech right of a researcher to try to persuade others about some matter of public concern.[190] The same is true with respect to this content-based application. In showing the subjects the films depicting smoking and deceiving them about his purpose in doing so, Professor Winston is not trying to persuade these subjects about some matter of public concern. Similarly, in signing up for this study and agreeing to watch these films, the subjects of the research are not participating in this speech by which we govern ourselves. It is worth repeating that the First Amendment does not—and should not—view subjects of research as autonomous and independent citizens engaged in self-governance. To the contrary, in many situations, including this one, they should be viewed as vulnerable subjects dependent on the researcher for their well being.[191]

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[187] *See* Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience*, 117 HARV. L. REV. 1765, 1768, 1778–84 (2004); *see also* Weinstein, *Speech Categorization*, *supra* note 97, at 1097–99; *supra* notes 93, 99 and accompanying text.

[188] *See* Ronald Dworkin, *The Curse of American Politics*, N.Y. REVIEW OF BOOKS, Oct. 1996, at 21 n.15 ("Constitutional lawyers often . . . say that all constraints on speech are banned in principle, and the exceptions must be justified, one by one, as special. But the vast range of acts of speech that are plainly not protected by the First Amendment makes it analytically clearer to say that it is protected speech that is special."); Schauer, *supra* note 187, at 1768 (observing that "even the briefest glimpse at the vast universe of widely accepted content-based restrictions on communication reveals that the speech with which the First Amendment deals is the exception and the speech that may routinely be regulated is the rule"). For a trenchant criticism of the All Inclusive Approach, both generally and as a method for determining the protection afforded scientific speech, see Robert Post, *Encryption Source Code and the First Amendment*, 15 BERKELEY TECH. L.J. 713, 715–17 (2000).

[189] Such an overextension will also likely have the unfortunate unintended consequence of diluting the strength of the protection afforded core First Amendment activity. *See* Weinstein, *Database Protection*, *supra* note 66, at 350.

[190] *See supra* notes 118–23 and accompanying text.

[191] *See supra* notes 121–23 and accompanying text. In contrast, a "subject" of an ordinary interview or survey conducted by a social science researcher is arguably no more dependent on the researcher or vulnerable to harm than is the "source" in an ordinary journalistic interview.

Of course, just because neither the speaker nor the audience is engaged in public discourse does not mean that a speech regulation cannot offend the democratic value underlying the First Amendment. For instance, a regulation that forbade researchers from exposing subjects to any material that would cause them to question the wisdom of the war in Iraq or to favor abortion rights would obviously offend this norm. But the content discrimination involved here is of an entirely different nature. Given the very real health and ethical concerns raised by this experiment, as well as the absence of any ideologically charged context,[192] there can be no real fear that the IRB is engaging in such forbidden ideological viewpoint discrimination in failing to approve Professor Winston's proposal.[193]

Thus if we focus narrowly on just the interests of Professor Winston and his subjects, the free speech values that the regulations implicate would seem similar to those implicated by health and safety restrictions on what physicians can communicate to their patients. Doctors sometimes deceive patients for their own good, such as by minimizing the catastrophic nature of a fatal disease. Suppose, however, that to protect patient autonomy and because it believes that lying is inherently immoral, a state medical licensing board issues a regulation forbidding such well meaning deception. One could argue that such a regulation unduly interferes with a physician's right to practice medicine. It is, however, very difficult to perceive what constitutionally protected free speech interests of the physician would be infringed by such a regulation,[194] and it is almost as difficult to imagine what free speech interests of the patient would be implicated.[195] Similarly, there would seem to be no constitutionally significant free speech values implicated if a psychiatrist were sued by the family of a patient who committed

[192] The situation might be different if tobacco companies were large donors to the university and there was reason to believe that the IRB denial was motivated by a desire not to jeopardize this funding or was a result of direct pressure from these companies.

[193] These same health concerns would most likely not be sufficient to ban images glorifying smoking in films distributed to the general public or to forbid deceptive or misleading documentary films. But that is because films distributed to the general public are, unlike those shown to subjects of a scientific experiment, part of "a structural skeleton that is necessary . . . for public discourse to serve the constitutional value of democracy." Post, *supra* note 96, at 1276; *see supra* notes 96–97 and accompanying text.

[194] *See* Daniel Halberstam, *Commercial Speech, Professional Speech, and the Constitutional Status of Social Institutions*, 147 U. PA. L. REV. 771, 845–46 (1999) (noting that because "the physician–patient relationship is marked by an imbalance of authority," speech in the physician–patient relationship "may be regulated in a manner that speech outside that context cannot"); *cf.* Bailey v. Huggins Diagnostic & Rehab. Ctr., Inc., 952 P.2d 768, 769 (Col. Ct. App. 1997) (upholding, in case in which a dentist was found liable for malpractice for recommending contrary to accepted dental practice removing amalgams containing mercury, the First Amendment right of another dentist to convey this view to the public in a book and a television interview).

[195] Restrictions on physician speech may interfere with the patient's interest in private decision-making. *See supra* notes 115–17 and accompanying text. But it is difficult to see how a law forbidding deception will interfere with this interest, unless the patient truly wants to be deceived.

suicide after watching a series of DVDs glorifying suicide that her doctor had given her as part of a course of treatment for depression.

It could be argued that the comparison to a doctor–patient relationship is inapt. Unlike the regulation of the communicative elements of the practice of medicine, which will usually affect neither the marketplace of ideas nor the information flow needed for public decision-making, IRB denial of Professor Winston's proposal to investigate the power of media to affect attitudes towards the risks of smoking may well interfere with the discovery of knowledge and possibly even information needed for public policy decisions such as media regulation. But we have been down this path before[196] and discovered that it leads to the "essential precondition of speech" argument examined and found wanting in Part I.[197] What distinguishes Professor Winston's speech from ordinary doctor–patient communication is that it is an essential part of a project that is likely to produce knowledge and might well yield information on matters of public concern. But so far as the impact on the marketplace of ideas and information needed for public decision-making is concerned, it does not matter that the IRB denied approval because of the communicative elements of his study as opposed to some noncommunicative element, such as the failure to obtain informed consent or to make the opportunity open to minorities or women. If the IRB had denied approval for any of these nonspeech related reasons, the impact on these free speech values would have been the same.

With respect to impairment of free speech values, then, Professor Winston is in precisely the same position as a biomedical researcher who wants to employ an invasive procedure to discover if certain biological factors influence the decision to begin smoking but is denied IRB permission to do so because the procedure might present a risk to the health of the subjects.[198] While these and various other techniques employed in social science experiments no doubt produce information that will enrich public discourse, so far as First Amendment values are concerned, these techniques are no different than procedures such as blood draws or PET scans used by biomedical researchers to produce information that will also contribute to public and private decision-making.[199]

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[196] *See supra* notes 44, 125 and accompanying text.

[197] *See supra* notes 21–42 and accompanying text.

[198] If the Court is not prepared to extend any free speech protection to biomedical research despite its undoubted contribution to the marketplace of ideas and information on matters of public concern, it is unlikely to extend such protection to social science research because this type of research arguably produces more information of public importance. And it would be illogical to do so for this reason just because social science involves more communication with subjects than does biomedical research. *See supra* p. 521.

[199] The fact that the experiment uses film to expose the subjects to these images does not alter this result. In its ordinary usage as a medium of mass communication, film is undeniably an important part of the "structural skeleton that is necessary . . . for public discourse to serve the constitutional value of

In the final analysis, the fact that the regulation preventing Professor Winston from conducting his research is a content-based rather than a content-neutral restriction is of no constitutional significance. What makes the regulation under consideration content based is that it is justified in terms of its impact *on the subjects of the study*. But as we have just seen, protecting subjects from the speech induced harms under consideration would not seem to implicate any constitutionally significant free speech norm. The content-based nature of the regulation has thus "spent its force" with respect to the subjects of the research, rendering its impact on the marketplace of ideas and the flow of public information analytically no different than a speech-neutral restriction.

So where does this analysis leave us with respect to the appropriate level of scrutiny applicable to the IRB's denial of approval to Professor Winston's study? It suggests that like content-based health and safety restrictions on communications from doctors to patients, the level of First Amendment scrutiny should be minimal. The extent of any judicial scrutiny should be to require the IRB to proffer some plausible, legitimate justification (speech related though it may be) for its decision, such as concern for protecting the legitimate health and safety of the subjects or ethics of the profession, as it did in this scenario. Such a justification would serve to dispel any possibility that an illegitimate reason, such as ideological disagreement with an idea expressed by the communicative element of the study, motivated the IRB's decision.[200] It would, in my view, be a serious mistake in cases such as these to apply any level of scrutiny that would require the judiciary to balance the need for the regulation against the free speech interest supposedly at stake. Where, as here, there is no core individual right implicated by the regulation and the impact on important instrumental free speech values is essentially no different from those imposed by restraints on biomedical research, balancing concerns such as protecting people from deception and health risks against the societal interest in the discovery of knowledge or the production of information relevant to public policy decisions is a task properly left to the legislature or its administrative delegate, in this case the IRB. Although there are good arguments that the IRB has not properly balanced these considerations in this case, the court should nonetheless reject Winston's First Amendment claim.

There may, however, be room for slightly greater judicial oversight where there is some reason to believe that "official suppression of ideas is afoot."[201] A regulation that may be vulnerable to a First Amendment challenge on this ground is the official interpretative guideline that directs IRBs

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democracy." Post, *supra* note 96, at 1276. However, when used in a psychological experiment like Professor Winston's, film has no such essential connection to democracy.

[200] This would be similar to the third step of the *O'Brien* test, but would require only a legitimate reason, not a speech neutral one. *See supra* note 149 and accompanying text.

[201] *See* R.A.V. v. City of St. Paul, 505 U.S. 377, 390 (1992).

in assessing risks to consider the "stress and feelings of guilt or embarrassment . . . aris[ing] . . . from thinking or talking about one's own behavior or attitudes on sensitive topics, such as drug use, sexual preferences, selfishness, and violence."[202] Consideration of such "soft" harms as "stress," "feelings of guilt" or "embarrassment" arising from thinking or talking about one's own behavior or attitudes on "sensitive topics" invites IRB members to smuggle their own ideological views into the review process. If the "sensitive topic" of the research is relatively ideologically neutral, such as attitudes towards incest or greed or cheating on examinations, the risks of ideological viewpoint discrimination would be slight. In such cases, the First Amendment scrutiny should be correspondingly minimal, the same as that which was applied to the denial of Dr. Winston's study of the effect of media images on attitudes towards smoking. But where the "sensitive topic" is ideologically charged, such as is the topic of "sexual preference" in today's world, and the harm to be avoided is something as nebulous as "stress," "feelings of guilt" or "embarrassment," more serious First Amendment scrutiny may be warranted.

Suppose, for instance, that a sociologist, Professor Money, wants to conduct a survey of undergraduate males about their sexual experiences and feelings about homosexual sex to support his hypothesis that the population of homosexual men is really much greater than supposed. The IRB, however, disapproves the study on the grounds that it might cause "stress," "feelings of guilt" and "embarrassment" to subjects who have had homosexual experiences but who nevertheless think of themselves as heterosexuals.[203] If interviews by social scientists on matters of public concern are entitled to the same First Amendment protection as journalistic interviews, then this restriction would obviously be unconstitutional if directly imposed by force of law rather than as a funding condition.[204] But even if the Court were to reject this view and instead subject IRB regulations of interviews to *O'Brien's* extremely deferential scrutiny or even to no First Amendment scrutiny at all, greater scrutiny is needed where, as in this example, IRB decisions are likely infected with the board members' own political ideology, such as views about the morality or social acceptability of homosexuality.

Of course, such pernicious viewpoint discrimination might also creep into IRB assessment of proposed research on a politically charged subject without significant communicative elements, such as research on whether homosexuality has a biological etiology. But the harms that would likely be

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[202] INSTITUTIONAL REVIEW BOARD GUIDEBOOK, *supra* note 153, at 3-1 to -10.

[203] *Cf. id*. at 3–4 (giving the following example of research that involves risk of psychological harm: "A social psychologist attached a psycho-galvanometer to subjects (male college students). The participants were told that the needle would be deflected if they were aroused, and that if the needle deflected when they viewed photographs of nude males, it would indicate latent homosexuality. Then false feedback was given so that the subjects were led to believe incorrectly that they were latent homosexuals. After the experiment, the ruse was explained.").

[204] *See supra* notes 127–28 and accompanying text.

caused by biomedical research, such as from blood draws or PET scans, are usually much "harder" and therefore more susceptible to objective assessment than are the "soft" psychological harms arising from communication with the subjects. Also, unlike politically controversial biological research or the application of a content-neutral IRB regulation to similarly controversial social science research, a content-based regulation such as the one under consideration could be applied out of fear that *the subject* will be influenced on some matter of social concern in a way that the IRB finds offensive. It is therefore conceivable that an IRB member might vote to disallow research on homosexual attitudes and behavior because he fears that the research itself will persuade some subjects that homosexuality is normal and socially acceptable.

Unlike truly content-neutral applications of IRB regulations, then, content-based ones like the one under discussion have the potential to impair the core democratic norm underlying the First Amendment. The fact that speech-induced harms tend to be softer than harm caused by conduct is alone grounds for concern that some illegitimate consideration will infect the analysis. But when this is combined with a regulation that, though perhaps innocent in intent, focuses on "sensitive topics," serious scrutiny is warranted, at least where the topic is highly ideological. Determining precisely what level of scrutiny is appropriate is a more difficult task.

Unless the Court decides to subject all interviews on matters of public concern to this standard, strict scrutiny, which has been aptly described as "'strict' in theory and fatal in fact,"[205] would be excessive.[206] The regulation (or more precisely, official interpretative guideline) is not on its face viewpoint oriented, and doubtless was not intended to authorize IRB members to reject research proposals because of ideological disagreements. In addition, "soft" though they may be, it is legitimate for IRBs to be concerned with mitigating stress, feelings of guilt, and embarrassment. Under these circumstances, though, it would be appropriate to put the burden on the IRB to show that the risk of these harms is fairly certain, and to demonstrate that alternative methods proposed by the investigator for reducing these risks will be substantially less effective. In addition, the researcher should be allowed to demonstrate that the IRB had not been as concerned about reducing similar harms in less politically charged research.

Legal formulas such as the scrutiny just described are, however, of limited practical value. The conclusion as to whether refusal to approve research on such ideologically sensitive topics as sexual preference is really a smoke screen for ideological viewpoint discrimination will in the final

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[205] Gerald Gunther, *The Supreme Court, 1971 Term—Foreword: In Search of Evolving Doctrine on a Changing Court: A Model for a Newer Equal Protection*, 86 HARV. L. REV. 1, 8 (1972) (internal citations omitted).

[206] Application of strict scrutiny would amount to ruling that because of its potential for inviting political viewpoint discrimination, this interpretative guideline is unconstitutional "on its face."

analysis depend on whether, in the judge's view, the IRBs explanation dispels the suspicion that it was engaged in "protecting" subjects from some disfavored ideology rather than from some harm which it has been legitimately charged with mitigating. Such a process is far too subtle to be either described or controlled by some precise verbal formula.[207]

In conclusion, the First Amendment guarantee of free speech imposes little constraint on even content-based applications of IRB regulations of many types of social science research. Although social science research typically contains expressive elements not present in biomedical research, the restrictions placed on these expressive elements will often no more implicate constitutionally cognizable free speech values than does IRB regulation of biomedical research. One exception calling for greater First Amendment scrutiny is IRB regulation of research that involves no more than ordinary interviewing methods such as surveys, questionnaires and oral inquiries intended to elicit information from the subjects on matters of public concern. In addition, substantial judicial oversight may be appropriate where circumstances suggest that a content-based restriction is really a smokescreen for ideological viewpoint discrimination against an idea expressed in some communicative element of the proposed research.

Such a modest judicial role is appropriate. If the gravamen of the complaint against IRB regulation is not that it interferes with researchers' right to express themselves on some matter of public concern but rather that it impedes the crucial public interest in the discovery of useful information, then the proper entity to adjust the balance between this public interest and the protection of human subjects is the legislature. This conclusion suggests that free speech may be entirely the wrong framework for testing whether IRB regulations interfere with some individual right protected by the Constitution.

III. RESEARCH AND THE RIGHT OF THOUGHT AND INQUIRY

In a recent article, Dana Irwin similarly concludes that freedom of speech guaranteed by the First Amendment is not a tenable source of a con-

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[207] Of course, such a nebulous level of scrutiny itself invites judges to smuggle their own ideological predispositions into the analysis, thus engaging in judicial viewpoint discrimination. *See* James Weinstein, *Free Speech, Abortion Access, and the Problem of Judicial Viewpoint Discrimination*, 29 U.C. DAVIS L. REV. 471, 474–90 (1996). This possibility presents another argument in favor of either total judicial abstention from the IRB field, even when the application of the regulation in question presents the specter of ideological viewpoint discrimination, or announcing an equally bright line rule that any requirement of prior approval of research consisting only of interviews on matters of public concern is unconstitutional. Federal judges, however, are by dint of their training and experience usually sensitive both to the danger and impropriety of allowing their own ideology to hold sway and, though by no means immune from this danger, are nonetheless less likely to succumb to this temptation than are IRB members.

stitutional right to research.[208] Rather, she locates such a right in the freedom of thought and inquiry protected by the First Amendment.[209] Although Irwin wisely eschews free speech as the source for a right to research, her attempt nevertheless to ground this right in the First Amendment is unpersuasive.

A. Substantive Due Process and Not the First Amendment as the Source for the Right to Research

Professor Irwin correctly notes that the Supreme Court has long held that the First Amendment protects a "sphere of intellect and spirit . . . reserve[d] from all official control."[210] It is not, however, at all clear that this protected sphere is broad enough to encompass a right to research. Almost all of the Supreme Court decisions cited by Irwin deal either with political or religious *belief*,[211] subject matter clearly within the First Amendment protection of speech and religion. And the few that do not concern such beliefs deal with sexually explicit *speech*.[212] A broader conception of freedom of thought, one that would include a general right of inquiry encompassing research, has no such connection to freedom of speech or religion or to any other liberty expressly spelled out in the text of the First Amendment or elsewhere in the Constitution. Accordingly, if such a right exists, it is more properly found within the unenumerated fundamental liberty interests pro-

[208] Irwin, *supra* note 20, at 1504. The focus of Irwin's article is not on the constitutional issues raised by IRB regulation but on restrictions on scientific experimentation generally. She notes the term "research" encompasses "reading, writing, discussing, and publishing activities that are protected as pure expression, independent of their connection to science," but warns that "these expressive elements can easily cloud the issue of whether the nonexpressive conduct of experimentation is protected." *Id*. at 1490. Parts I and II of this Article demonstrated that, "publishing activities" aside, the expressive elements of research are not likely to endow that activity with much First Amendment protection against IRB regulation. *See* discussion *supra* Parts I and II.

[209] Professor Hamburger notes but does not pursue the possibility that the First Amendment protects freedom of research or inquiry apart from the protection he believes is bestowed by freedom of speech. *See* Hamburger, *supra* note 2, at 306 n.94.

[210] Irwin, *supra* note 20, at 1511 (quoting W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943)).

[211] Irwin *supra* note 20, at 1508–15 (citing and discussing Schneider v. Smith, 390 U.S. 17 (1968) (upholding right of an applicant to the merchant marines to not have to answer questionnaire inquiring into applicants beliefs and associations); *Barnette*, 319 U.S. 624 (recognizing right of school children not to salute flag); Wooley v. Maynard, 430 U.S. 705 (1977) (finding that the First Amendment protects individuals from being compelled to display an ideological slogan on vehicle license plate); Elrod v. Burns, 427 U.S. 347 (1976) (recognizing right of public employees to be free from pressure to belong to or contribute to a political party in order to maintain their jobs); Branti v. Finkel, 445 U.S. 507 (1980) (holding that public employees cannot be dismissed solely for their political affiliations); Rutan v. Republican Party, 497 U.S. 62 (1990) (extending *Elrod* prohibitions on political patronage requirements to job promotion, transfer, recall and hiring decisions)).

[212] Irwin, *supra* note 20, at 1508–10 (citing and discussing Stanley v. Georgia, 394 U.S. 557 (1969) (recognizing the right to possess obscene material in one's own home) and Paris Adult Theatre I v. Slaton, 413 U.S. 49, 67 (1973) (holding that a law prohibiting distribution of obscene material restricts action, not thought)).

tected by the Due Process Clauses of the Fifth and Fourteenth Amendments.

Read literally, the Due Process Clauses of the United States Constitution assure only that government afford people certain procedural safeguards before depriving them of liberty.[213] Nonetheless, under its so called "substantive due process" jurisprudence, the Court has long held that these provisions also restrict government from infringing certain unenumerated fundamental substantive rights.[214] These fundamental liberty interests include reproductive freedoms such as the right to use contraception[215] or to abort a pregnancy,[216] and rights of intimate association such as the right to marry[217] or to live in extended families[218] or of parents to make decisions concerning the "care, custody and control" of their children.[219]

In recent years, however, the Court has been reluctant to extend this select list of unenumerated fundamental liberty interests, refusing, for instance, in 1997 to recognize a fundamental liberty interest of even terminally ill people to determine the time and manner of their death.[220] As the Court had earlier explained:

> Nor are we inclined to take a more expansive view of our authority to discover new fundamental rights imbedded in the Due Process Clause. The Court is most vulnerable and comes nearest to illegitimacy when it deals with judge-made constitutional law having little or no cognizable roots in the language or design of the Constitution . . . . There should be, therefore, great resistance to

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[213] The Fifth Amendment, which is applicable only to the federal government, provides that "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law . . . ." U.S. CONST. amend. V. The Fourteenth Amendment reads: "nor shall any State deprive any person of life, liberty, or property, without due process of law." U.S. CONST. amend. XIV § 1.

[214] *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 846 (1992) ("Although a literal reading of the [Due Process] Clause [of the Fourteenth Amendment] might suggest that it governs only the procedures by which a State may deprive persons of liberty, . . . at least since [1887] the Clause has been understood to contain a substantive component as well . . . .").

[215] *See* Carey v. Population Servs. Int'l, 431 U.S. 678 (1977); Griswold v. Connecticut, 381 U.S. 479 (1965).

[216] *See Casey*, 505 U.S. 833; Roe v. Wade, 410 U.S. 113 (1973).

[217] *See* Turner v. Safley, 482 U.S. 78 (1987); Zablocki v. Redhail, 434 U.S. 374 (1978).

[218] *See* Moore v. City of East Cleveland, 431 U.S. 494 (1977).

[219] *See* Troxel v. Granville, 530 U.S. 57 (2000); Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925).

[220] *See* Washington v. Glucksberg, 521 U.S. 702 (1997); *see also* Tenet v. Doe, 544 U.S. 1, 5, 10–11 (2005) (rejecting claim on stare decisis grounds that the CIA violated respondents "procedural and substantive due process rights by denying them support and by failing to provide them with a fair internal process for reviewing their claims" under the state secrets privilege); Reno v. Flores, 507 U.S. 292, 302–03 (1993) (rejecting the "right of a child who has no available parent, close relative, or legal guardian, and for whom the government is responsible, to be placed in the custody of a willing-and-able private custodian rather than of a government-operated or government-selected child-care institution"); Collins v. City of Harker Heights, 503 U.S. 115, 125–26 (1992) (rejecting a right of municipal employees to a "reasonably safe work environment" based on the Due Process Clause of the Fourteenth Amendment); DeShaney v. Winnebago Cty. Dep't of Soc. Servs., 489 U.S. 189, 194–95 (1989) (rejecting a minor's right to adequate state protection from an abusive parent).

> expand the substantive reach of [the Due Process Clauses of the Fifth and Fourteenth Amendments], particularly if it requires redefining the category of rights deemed to be fundamental. Otherwise, the Judiciary necessarily takes to itself further authority to govern the country without express constitutional authority.[221]

There is thus reason to doubt that the Court would recognize a right to research as a liberty specially protected by the Due Process Clauses.[222] But even if we were to assume that the Court would recognize such a right, very difficult questions remain as its scope and weight.

B. The Scope of a Right to Research Derived from the Right of Thought and Inquiry

With respect to the scope of the right, Professor Irwin is surely correct that if this right exists at all, it must include at least the right to engage in an experiment consisting of "pure thought with no accompanying action," such as Schrödinger's famous thought experiment.[223] But once we move beyond thought experiments to *conduct* that either manifests or aids scientific thought and inquiry, it is very difficult to know where to draw the line between protected and unprotected activity.

One obvious solution is to draw a sharp and formal distinction between thought and conduct. Under this approach, pure thought would be immune from government regulation, while any physical manifestation of this thought or any activity aiding it would be regulable. Because such a dichotomy would be easy to administer, there is a significant possibility that the Court would adopt it, at least as a formal matter. The problem with this approach is that any such right would be so narrow as to be practically useless. By its very nature, pure thought not manifested by any conduct is very difficult for government to control, and consequently is in need of very little

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[221] Bowers v. Hardwick, 478 U.S. 186, 194–95 (1986); *see also* Regents of Univ. of Mich. v. Ewing, 474 U.S. 214, 223–26 (1985) ("Although the Court regularly proceeds on the assumption that the Due Process Clause has more than a procedural dimension, we must always bear in mind that the substantive content of the Clause is suggested neither by its language nor by preconstitutional history; that content is nothing more than the accumulated product of judicial interpretation of the Fifth and Fourteenth Amendments." (quoting Moore v. East Cleveland, 431 U.S. 494, 543–44 (1977) (White J., dissenting))). *Bowers* held that there was no fundamental right to engage in homosexual sodomy. Although in Lawrence v. Texas, 539 U.S. 558, 578 (2003), the Court subsequently found that criminal sanctions against adults engaged in consensual homosexual sodomy violated the Due Process Clause of the Fourteenth Amendment, it sedulously avoided declaring that there was a fundamental right to engage in such activity. *See infra* note 240 and accompanying text.

[222] This is likely the reason that commentators have long tried to derive a right of research from the Free Speech Clause of the First Amendment and why Professor Irwin, though properly recognizing that such a right does not reside there, nonetheless invokes the First rather than the Fifth and Fourteenth Amendments as the source for this right.

[223] Irwin, *supra* note 20, at 1479.

protection against government intrusion.[224] In any event, such a narrow conception of the right of inquiry would give no protection against IRB regulations, no matter how draconian or unreasonable.

The other obvious place to draw the line is at the opposite end of the spectrum. Under this approach, investigators would have a right to engage in any research or experiment that contributes to solving whatever problem they are working on.[225] Such a right, however, is not as broad as it might first appear. Even if virtually all conduct that facilitates inquiry were considered to be within the scope of this right, not every regulation that impedes this conduct would infringe, let alone violate, the right. As the Court has explained, not every regulation "which relates in any way" to a fundamental right is an infringement that "must be subjected to rigorous scrutiny."[226] Rather, only regulations that interfere "directly and substantially" with a liberty interest are considered infringements of the right in question.[227]

Irwin usefully proposes that a regulation that "forecloses an entire line of inquiry" such as "a complete prohibition of a certain form of experimentation" should be considered a "direct" intrusion, while a regulation that merely "dictates the manner or means by which an experiment is preformed" should be deemed an "incidental" one.[228] Under this framework, a ban, say, on stem cell research or human cloning would be a direct intrusion on, and thus an infringement of, the right of inquiry. Conversely, a law that prohibited the use of stem cells taken from human embryos created specifically for the purpose of providing these cells would be considered only an incidental intrusion and thus, unless excessively and unreasonably burdensome,[229] would not be considered an infringement on the right. Even more indirect would be laws or regulations of general applicability, such as a ban on the use of highly toxic substances regardless of the experiment for which they are used.

How would IRB regulations fit within this proposed framework? Arguably, the entire IRB system is merely a restriction on "the manner or

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[224] One means by which government might interfere with thoughts is by requiring people seeking some government job or benefit to answer questions concerning their beliefs. *See, e.g.*, Schneider v. Smith, 390 U.S. 17 (1968).

[225] It would be quite difficult to draw a principled and workable line at any intermediate point on this continuum. For instance, if it infringes the right of inquiry to prohibit writing down one's thoughts in order to facilitate solving a problem, how can a ban on the use of a computer for the same purpose not do so? Conversely, if the state can constitutionally ban cloning of humans, why can't it prohibit a procedure that comes right to the edge of the forbidden result, such as cloning a chimpanzee?

[226] Zablocki v. Redhail, 434 U.S. 374, 386 (1978).

[227] *Id*. at 387.

[228] Irwin, *supra* note 20, at 1525.

[229] *See infra* notes 231–32 and accompanying text. Irwin actually proposes that *any* indirect burden be subject to intermediate scrutiny, a view that is inconsistent with the Court's fundamental rights jurisprudence.

means" by which the research is performed—the use of human subjects—and not an attempt to foreclose any particular "line of inquiry."[230] Thus any of the individual IRB regulations, including the basic requirement that investigators conducting research on human subjects obtain approval before conducting such research, would be considered "indirect" and thus presumptively not an infringement of the right to inquiry. But this does not mean that IRB regulations are immune from challenge as a violation of the right to inquiry. Under the Court's substantive due process jurisprudence, not only are outright prohibitions of fundamental rights considered infringements, but so too are regulations that substantially burden these rights. For instance, in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Court found that a law requiring a woman to inform her spouse that she is about to undergo an abortion was an "undue burden" on her right to obtain an abortion.[231] Similarly, a regulation that imposes a substantial burden on a researcher's ability to explore a line of research would seem to infringe the constitutional right of inquiry.[232]

Just how significant a burden the regulation of research would have to be to constitute an infringement of the right of inquiry, thereby requiring the state to justify the regulation, is a crucial question. Given the Court's reluctance to recognize any additional unenumerated fundamental rights and the obviously legitimate reasons for regulating research using human subjects, it is likely that if the Court were to recognize a right to research it would find only exceedingly burdensome regulations to infringe that right. An example of such a regulation might be an IRB decision that, although not in terms "foreclos[ing] an entire line of inquiry,"[233] effectively did so. Such a situation might arise if an IRB disapproved a project because the risks of the research to human subjects outweighed the benefits and it was not possible to redesign the project to reduce the risks or eliminate the use of human subjects altogether. Similarly, a long delay in approving a time sensitive project, or the imposition of some impossible to fulfill condition—such as requiring illiterate subjects to read and sign an informed consent form—might be considered an "undue burden" on and hence an infringement of the right to research.

But just because a regulation infringes a fundamental right does not mean that the regulation is unconstitutional.[234] Whether the regulation violates a right depends upon whether the government has an adequate justifi-

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[230] Irwin, *supra* note 20, at 1525.

[231] 505 U.S. 833, 887–99 (1992).

[232] As the adjective "undue" suggests, a finding of an undue burden means not only that the right has been significantly burdened but that the burden is unjustified and thus violates the right. Whether a right is infringed, in contrast, depends only on the degree of burden, not the justification for the burden. The Court's abortion jurisprudence often conflates these two separate analytical steps.

[233] Irwin, *supra* note 20, at 1525.

[234] *See supra* notes 226–27 and accompanying text.

cation for the infringement, a question that in turn depends in large part on the weight of the right in question.[235]

C. The Weight of the Right to Research

The Supreme Court's substantive due process jurisprudence is marked by a stark all or nothing approach to the weight it assigns liberty interests. Fundamental liberty interests are given an extremely heavy weight: Infringements of these interests will be upheld only if the infringement is "narrowly tailored" to serve a "compelling" state interest.[236] Such scrutiny has been well characterized as "'strict' in theory and fatal in fact."[237] In sharp contrast, if a liberty interest is not deemed fundamental but rather is considered a "mere" liberty interest, the government may infringe this interest if it has a legitimate interest for doing so that is rationally related to the regulation.[238] Such scrutiny has been aptly deemed "minimal . . . in theory and virtually none in fact."[239] One case that does not fit this bipolar pattern is the Court's recent decision in *Lawrence v. Texas*, which held unconstitutional a Texas law criminalizing homosexual sodomy.[240] Though giving considerable constitutional protection to this activity, the Court avoided deeming it a "fundamental right" or applying the concomitant strict scrutiny.

Professor Irwin proposes that any direct infringement of the right to research be subject to strict scrutiny.[241] I am fairly confident, however, that if the Court were to recognize a right to research as broad as the one under consideration (which is itself subject to considerable doubt), it would not give this right the prodigious weight it has afforded fundamental liberties such as reproductive freedoms, the right to marry, or the right of parents to make decisions concerning their children.[242] Rather, for several reasons, the

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[235] *See* Youngberg v. Romeo, 457 U.S. 307, 320 (1982) ("In determining whether a substantive right protected by the Due Process Clause has been violated, it is necessary to balance 'the liberty of the individual' and 'the demands of an organized society.'") (quoting Poe v. Ullman, 367 U.S. 497, 542 (1961) (Harlan, J., dissenting)).

[236] *See* Washington v. Glucksberg, 521 U.S. 702, 721 (1997) ("[T]he Fourteenth Amendment 'forbids the government to infringe . . . fundamental liberty interests . . . unless the infringement is narrowly tailored to serve a compelling state interest.'" (quoting Reno v. Flores, 507 U.S. 292, 302 (1993)).

[237] *See* Gunther *supra* note 205, at 8.

[238] *See, e.g.*, *Glucksberg*, 521 U.S. at 728 (holding that because assistance in committing suicide "is not a fundamental liberty interest" the ban on assisted suicide at issue would be constitutional if "rationally related to a legitimate government interest.").

[239] Gunther, *supra* note 205, at 8 (internal quotations omitted).

[240] 539 U.S. 558 (2003).

[241] She also suggested that the Court has subjected incidental restrictions to intermediate scrutiny. Irwin, *supra* note 20, at 1515–18. In my view, an incidental restriction would be subject to a rational basis test.

[242] In the abstract, the right of inquiry may be as fundamental to human dignity and autonomy as the right to control one's procreation or to raise a child. Nonetheless, the Court would likely find that even a total ban on a line of research is not nearly as direct an intrusion on the right of inquiry as is, for in-

Court is more likely to give this interest the ambiguous weight it afforded the right in *Lawrence* or perhaps even expressly recognize the existence of middle-weight liberty interests. Accordingly, if the Court were to recognize a broad right to research, it would likely subject direct infringements of the right to some form of "intermediate scrutiny," which requires that government demonstrate the restriction is substantially related to an important governmental interest.[243]

To appreciate the improbability of the Supreme Court applying strict scrutiny to all direct infringements on the right to research, consider a ban on human cloning. Government may well have legitimate and even important reasons for such a ban, including preventing the creation of a people subject to deformity and premature aging or to psychological problems such as a diminished sense of individuality.[244] But none of these interests are "compelling,"[245] at least not as that term has been used in the Court's substantive due process jurisprudence.[246] The cautious tenor of the Supreme Court's contemporary substantive due process jurisprudence, however, makes it extremely doubtful that a ban on human cloning would come to the Court with the strong presumption against its validity inherent in a strict scrutiny analysis. Rather, at most, the Court would balance the relevant interests without any presumption about the constitutionality of the regulation, a mode of analysis captured by intermediate scrutiny. Indeed, because of the difficult health and safety issues that would often be present in most right to research cases, any presumption might well be in favor of the constitutionality of such laws. Under such a lenient form of intermediate scrutiny, the Court would likely uphold the ban, finding each of the asserted interests for banning cloning sufficiently important and the ban to be sufficiently related to those interests.[247]

Still, the recognition of even a middle-weight liberty interest would afford some protection against excessively burdensome IRB regulation. As

stance, a ban on abortion on a woman's right to bodily integrity and decisional autonomy. Looking to the other side of the equation, the Court would likely doubt its institutional competence to accurately assess the dangers that might arise from unconstrained research.

[243] *See supra* text accompanying notes 148–149.

[244] *See* Irwin, *supra* note 20, at 1528–29.

[245] Surely the "diminished sense of individuality" that might affect identical twins would not be sufficient grounds to force a woman pregnant with twins to abort one of them. Nor is the fact that a fetus is certain (let alone at risk) to be born with a serious physical defect a compelling enough reason to force his mother to abort the pregancy.

[246] Professor Irwin presents one arguably compelling reason for such a ban—a decreased variation in the human gene pool, "leaving humans more vulnerable to disease and adverse environmental conditions." Irwin, *supra* note 20, at 1529. However, a solution to these problems could easily be found by far less intrusive means, such as limiting the number of clones that could legally be produced.

[247] Interestingly, Irwin also concludes that the Court would, despite the application of strict scrutiny, uphold a ban on human cloning. *Id*. at 1530. This conclusion puts into doubt whether, despite use of the label "strict scrutiny," Irwin's analysis really subjects the ban to the rigorous review the Court usually applies under that rubric.

discussed above, IRB decisions that effectively deny investigators the ability to pursue their research may well constitute an infringement of the right to inquiry. If the justification for the denial of permission to conduct the research is weak, for instance, if the likely harm to the subjects were either insubstantial or extremely remote, then the denial might well fail intermediate scrutiny, thus violating the right to research.[248] The same might be true of some mindless application of a rule, such as requiring written consent from illiterate people or where obtaining such consent would endanger rather than protect the subjects.[249]

Though this moderate weight liberty interest would provide some protection against extremely burdensome but weakly justified applications of IRB regulations, such protection would be limited. For one, it would not offer a basis for attacking the IRB regulations on their face but only as applied. Additionally, it would not provide protection against only modestly burdensome restraints on the right to research or even complete denials if the IRB could show an important interest for not approving the project. And prevention of even most types of harm to human subjects would easily qualify as an important interest. Significantly, however, under such an analysis, one category of injuries that might not qualify as sufficiently important interests, except in the extreme cases, is "soft" harms such as embarrassment, stress, and feelings of guilt.[250]

IV. CONDITIONAL SPENDING ISSUES

In order to expose any constitutional problems with IRB regulations, the discussion so far has assumed that these restrictions were imposed directly on research institutions by force of law rather than, as is actually the

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[248] As discussed above, the First Amendment would not afford even this modest level of protection for research except, possibly, if the research consisted solely of traditional interviewing techniques. *See* discussion *supra* notes 54–60, 82–83, 125 and accompanying text. But this difference is proper because unlike the interest in truth discovery in the marketplace of ideas or even information flow needed for public decision-making, the right of inquiry involves interests of identifiable individuals.

[249] *See supra* notes 161–71 and accompanying text. Although not of particular concern to constitutional limitations on IRB regulations, it is worth noting that a likely consequence of deeming the interest in engaging in research a constitutional right of even modest weight would be to prevent government from banning research purely on moral grounds. *See* Lawrence v. Texas, 539 U.S. 558, 571–74, 578 (2003) (holding that the government's general interest in morality is not sufficient to prohibit the exercise of a liberty interest specially protected by the Due Process Clause of the Fourteenth Amendment); *see also* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 850 (1992) (moral opposition is not sufficient to infringe or unduly burden a woman's right to obtain a pre-viability abortion). Obtaining such special protection for a liberty interest, be it designated "fundamental," "quasi-fundamental" or by any other term, is crucial, for it is well established that the government's interest in morality *is* sufficient justification for infringing a "mere" liberty interest. *See* Paris Adult Theatre I v. Slaton, 413 U.S. 49, 60–61 (1973) (holding that except where legislation "impinges upon rights protected by the Constitution" government can "legitimately act . . . to protect 'the social interest *in order and morality*'") (quoting Roth v. United States, 354 U.S. 476, 485 (1957))).

[250] *See supra* note 175 and accompanying text.

case, through a condition on receipt of federal support for research at these institutions. To complete the analysis, I shall now consider the significance of the conditional nature of these regulations. To the extent that IRB regulations can constitutionally be imposed directly, no further constitutional issues are raised by the fact that these regulations are imposed as funding conditions. As the Court has recently explained, "a funding condition cannot be unconstitutional if it could be constitutionally imposed directly."[251] To the extent, however, that direct regulation would be unconstitutional, either as a violation of the First Amendment or substantive due process, the fact that these regulations are imposed as a condition of federal funding might avoid these constitutional problems. As the Supreme Court has also explained, "Congress has wide latitude to attach conditions to the receipt of federal assistance in order to further its policy objectives."[252] But, of course, the conditional nature of the regulation can obviate these constitutional difficulties only if the conditions themselves are constitutional. This is the question that I shall address in this final Part.

Wide though it may be, Congressional latitude to attach conditions to the receipt of federal funds is not unlimited. Federal spending authority is confined by the doctrine of "unconstitutional conditions," a doctrine that has particular bite when the condition implicates individual constitutional rights.[253] "In the speech context, the Court has [applied this doctrine] by distinguishing denials of benefits that operate as 'penalties' on speech from those that operate as mere 'nonsubsidies.'"[254] The Court has also adopted a similar analysis with respect to conditional funding affecting substantive

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[251] Rumsfeld v. Forum for Academic and Institutional Rights, 126 S. Ct. 1297, 1307 (2006).

[252] United States v. Am. Library Ass'n, 539 U.S. 194, 203 (2003) (plurality opinion).

[253] While the question under consideration here as well as in most of the recent Supreme Court unconstitutional condition cases involve conditions on federal subsidies, the doctrine also applies to state and local subsidies. *See, e.g.*, Speiser v. Randall, 357 U.S. 513 (1958). There is, however, a conceptually similar doctrine applicable only to the federal government that imposes internal limits on Congress's power to spend for the general welfare under Article I, Section 8 of the Constitution. *See, e.g.*, South Dakota v. Dole, 483 U.S. 203 (1987). These federalism cases are even more deferential to Congress than the decisions involving spending conditions affecting individual rights—so much so that the Court has not invalidated a spending program on federalism grounds since striking down a New Deal provision in 1936. *See* United States v. Butler, 297 U.S. 1 (1936). Accordingly, if a spending provision imposing a restriction on speech or some other individual right does not violate the First Amendment, it is highly unlikely that it would violate the even less restrictive federalism limitations. Still, whether a spending condition imposes a "penalty" on an individual right is, in the final analysis, distinct from the question of whether by imposing the condition Congress has exceeded its spending power. *See infra* notes 257–76 and accompanying text. It is therefore theoretically possible, though most unlikely, that even if consistent with the First Amendment and substantive due process, the IRB conditions attached to federal spending are unconstitutional on federalism grounds.

[254] SULLIVAN & GUNTHER, *supra* note 39, at 1319; *see also* Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413, 1420 (1989) (observing that "conditioned benefits are frequently deemed 'penalties' when struck down and 'nonsubsidies' when upheld").

due process rights.[255] In addition to prohibiting government from using funding conditions to "penalize" recipients for the exercise of their own constitutional rights, the unconstitutional conditions doctrine prevents government from "inducing" the recipient to engage in activities that would violate the constitutional rights of others or are otherwise unconstitutional activities.[256]

A. *Federal Research Funding Conditions Requiring IRBs: "Penalty" or "Nonsubsidy"?*

As a leading authority on unconstitutional conditions has observed, when the Court decides whether a funding condition is a "penalty" or a mere "nonsubsidy," "[c]onclusory labels often take the place of analysis."[257] Moreover, the entire doctrine of unconstitutional conditions is "riven with inconsistencies" and is thus "a minefield to be traversed gingerly."[258] Still, there are several salient features that emerge from the case law, the most prominent of which is a focus on the "germaneness" of the condition to the benefit.[259] This concept is captured in recent conditional spending cases by the focus on whether the condition can be seen as a reasonable means of assuring that "'public funds be spent for the purposes for which they were authorized'"[260] rather than as an attempt to prevent the recipient from "engaging in the [constitutionally] protected conduct outside the scope of the federally funded program."[261] A related feature of the funding cases involving speech restrictions, but which would also be pertinent to a challenge based on the substantive due process right to research, is whether the condition is aimed at "'suppression of dangerous ideas.'"[262]

Speiser v. Randall[263] is instructive on both of these key features of the Court's unconstitutional conditions jurisprudence. *Speiser* invalidated a California law that made property tax exemptions for veterans available only to those who declared that they do not advocate the forcible overthrow of the government. In striking down the law, the Court rejected the argument that "because a tax exemption is a 'privilege' or 'bounty,' its denial may not infringe speech," holding rather that the condition imposed on re-

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[255] *See, e.g.*, Harris v. McRae, 448 U.S. 297, 317 & n.19 (1980); Maher v. Roe, 432 U.S. 464, 474–75 & n.8 (1977).

[256] *Am. Library Ass'n*, 539 U.S. at 203 (plurality opinion).

[257] Sullivan, *supra* note 254, at 1420.

[258] *Id*. at 1416.

[259] *Id*. at 1420.

[260] *Am. Library Ass'n*, 539 U.S. at 212 (plurality opinion) (quoting Rust v. Sullivan, 500 U.S. 173, 196 (1991)); *see also id.* at 203 ("Congress has wide latitude to attach conditions to the receipt of federal assistance in order to further its policy objectives.").

[261] *Rust*, 500 U.S. at 197.

[262] Regan v. Taxation with Representation, 461 U.S. 540, 548 (1983) (quoting Cammarano v. United States, 358 U.S. 498, 513 (1959)).

[263] 357 U.S. 513 (1958).

ceipt of the benefit must be "'reasonable.'"[264] Finding that the denial of the tax exemption at issue was "'frankly aimed at the suppression of dangerous ideas,'"[265] the Court held that the denial was not reasonable but rather "penalize[d]" those who wished to express such ideas.[266]

Speiser did not elaborate upon what constitutes a "reasonable" denial of a subsidy rather than a penalty on the expression of ideas.[267] Two features of the law at issue in that case standout, however. First, there was no obvious connection between the government's legitimate objective in offering property tax exemptions for veterans and the condition that the veterans not advocate the overthrow of the government. In addition, the regulation was on its face ideologically viewpoint oriented. The combination of targeting unpopular speech and the lack of any nexus between the purpose of the program and the condition left little doubt that the condition served no legitimate purpose, but rather was calculated to coerce people to relinquish their right to express constitutionally protected ideas.[268]

Subsequent conditional funding cases involving conditions on speech continue to inquire whether or not the condition is "'aim[ed] at the suppression of dangerous ideas.'"[269] And these cases are more explicit about the germaneness criterion, focusing on whether the condition can reasonably be viewed as a means of assuring that expenditure promotes the purpose of the program.[270] Because these cases give government wide leeway to define the limits of any program it funds,[271] the Court usually upholds spending conditions, even when they restrict speech. Thus the Court has sustained the de-

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[264] *Id*. at 518.

[265] *Id*. at 519 (quoting Am. Commc'ns Ass'n v. Douds, 339 U.S. 382, 402 (1950)).

[266] *Id*. at 518.

[267] Nor did the Court do so in *Grove City Coll. v. Bell*, 465 U.S. 555 (1984), which summarily rejected a college's claim that conditioning receipt of federal funds on compliance with Title IX of the Education Amendments of 1972 violated the First Amendment. Rather, the Court simply stated that "Congress is free to attach reasonable and unambiguous conditions to federal financial assistance that educational institutions are not obligated to accept." *Id.* at 575.

[268] Dicta in the abortion funding cases underscores the centrality of the germaneness criterion in funding cases involving substantive due process rights. In upholding a Connecticut regulation extending Medicaid benefits for childbirth but denying benefits for nontherapeutic abortions, the Court stated: "If Connecticut denied general welfare benefits to all women who had obtained abortions and who were otherwise entitled to the benefits," the denial of benefits might constitute a "penalty" on the right to abortion. Maher v. Roe, 432 U.S. 464, 474–75 n.8 (1977); *see also* Harris v. McRae, 448 U.S. 297, 317 & n.19 (1980) ("A substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits from an otherwise eligible candidate simply because that candidate had exercised her constitutionally protected freedom to terminate her pregnancy by abortion.").

[269] *See* Nat'l Endowment for the Arts v. Finley, 524 U.S. 569, 587 (1998) (quoting Regan v. Taxation with Representation, 461 U.S. 540, 548 (1983)); Rust v. Sullivan, 500 U.S. 173, 192 (1991).

[270] *See* United States v. Am. Library Ass'n, 539 U.S. 194, 203 (2003) (plurality opinion) ("Congress has wide latitude to attach conditions to the receipt of federal assistance in order to further its policy objectives."); *id*. at 211–12 ("Congress may certainly insist that these 'public funds be spent for the purposes for which they were authorized.'" (quoting *Rust*, 500 U.S. at 196)).

[271] *See Am. Library Ass'n*, 539 U.S. at 203 (plurality opinion).

nial of tax benefits to organizations engaged in lobbying;[272] a prohibition forbidding projects receiving federal family planning funds from counseling or advocating abortion;[273] a requirement that the federal agency charged with funding arts projects take into consideration "general standards of decency and respect for the diverse beliefs and values of the American public";[274] and a federal law that required libraries receiving federal assistance for Internet access to install software to block obscene and pornographic images.[275] Similarly, the Court has uniformly upheld spending conditions restricting liberties deemed fundamental under its substantive due process jurisprudence.[276]

Judged by these standards, the condition that research institutions establish an IRB and apply the Common Rule[277] to all projects actually receiving federal funds would easily pass constitutional muster. The wide authority that Congress has to define the limits of its funding programs includes the authority to limit its support to ethical research in which human subjects are not put at unnecessary risk. In addition, enforcing these limits by insisting that specific procedures be put in place and that particular rules and standards be followed is reasonably related to achieving this end. That certain applications of these rules might be contrary to good social policy or even occasionally be used to restrict speech does not make these conditions any less constitutional on their face.[278] Nor can there be any pretense here that these limitations are really "aim[ed] at the suppression of dangerous ideas."[279]

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[272] *See Taxation with Representation*, 461 U.S. 194.

[273] *See Rust*, 500 U.S. at 192–201.

[274] *Finley*, 524 U.S. at 572 (quoting 20 U.S.C. § 954(d)(1) (1988)).

[275] *See Am. Library Ass'n*, 539 U.S. at 210–14 (plurality opinion). The one spending case pertinent to our inquiry in which the Court found a condition unconstitutional is *FCC v. League of Woman Voters of Cal.*, 468 U.S. 364 (1984), discussed *infra* notes 281–97.

[276] *See Rust*, 500 U.S. at 201; Webster v. Reproductive Health Servs., 492 U.S. 490, 507–11 (1989); Harris v. McRae, 448 U.S. 297, 312–18 (1980); Poelker v. Doe, 432 U.S. 519, 521 (1977); Maher v. Roe, 432 U.S. 464, 471–78 (1977).

[277] *See supra* note 1.

[278] *See Finley*, 524 U.S. at 587.

[279] *Id*. at 587 (quoting Regan v. Taxation with Representation, 461 U.S. 540, 548 (1983)). Because IRB regulations do not facially discriminate on the basis of speakers' viewpoint, the validity of the spending restriction is not put in question by *Rosenberger v. Rector & Visitor of University of Virginia*, which invalidated a facially viewpoint discriminatory limitation imposed by a public university on the expenditure of funds to support student publications. 515 U.S. 819, 831 (1995). In addition, unlike federal research support, the funds in *Rosenberger* were used to create a "limited public forum," *id*. at 829, a setting in which government's ability to restrict speech is particularly circumscribed. *See, e.g.*, Lamb's Chapel v. Center Moriches Union Free School Dist., 508 U.S. 384 (1993). To the extent, however, that IRB regulations are applied in an ideologically viewpoint discriminatory fashion, *Rosenberger* suggests that the fact that IRB regulation is imposed as a condition of funding rather than directly by force of law will not cure what would otherwise be an unconstitutional application of the regulations. *See infra* note 304.

More vulnerable to attack as an unconstitutional condition is the further requirement that even nonfederally funded research at an institution receiving federal research funds is subject to either IRB review or to an "ethical principle" developed by the institution and approved by the government.[280] In *FCC v. League of Women Voters of California*,[281] the Court invalidated a federal law forbidding any noncommercial educational radio station receiving a grant from the Corporation for Public Broadcasting ("CPB") from engaging in editorializing. The Court noted that a station that received only 1% of its income from CPB grants is "barred absolutely from all editorializing."[282] The Court distinguished *Regan v. Taxation with Representation*,[283] which upheld the denial of tax benefits to organizations engaged in lobbying, noting that while those organizations in that case could establish an affiliate that was permitted to engage in lobbying, the stations here were "not able to segregate according to its source of funding."[284] In a subsequent case, the Court elaborated on the importance of this distinction: "[O]ur '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."[285]

It could be argued that like the condition invalidated in *League of Women Voters*, the condition that even nonfederally funded projects be subject to IRB regulations or some other ethical principle is an attempt by the government to leverage its authority to impose limits on a program that it funds to prohibit the entire institution from "engaging in the [constitutionally] protected conduct outside the scope of the federally funded program."[286] But requiring that all researchers at an institution follow at least basic ethical principles regarding the treatment of human subjects seems reasonably related to protecting subjects in federally funded projects. Allowing Dr. Jones to use human subjects unconstrained by any formal ethical guidelines will arguably undermine Dr. Smith's compliance with the IRB standards in the laboratory next door, especially if the two scientists are in competition with each other. More generally, the existence of researchers at an institution unconstrained by any formal ethical standards might negatively affect the ethical ethos of the entire institution, leading to an ethical

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[280] *See* 45 C.F.R. § 46.103(b)(1) (2005).

[281] 468 U.S. 364 (1984).

[282] *Id*. at 400.

[283] 461 U.S. 540.

[284] *League of Women Voters*, 468 U.S. at 400.

[285] Rust v. Sullivan, 500 U.S. 173, 197 (1991). Like the organizations in *Taxation with Representation*, the recipients of funds in *Rust* could continue to advocate abortion outside of the project. *See id.* at 198–99.

[286] *Id*. at 197. Professor Hamburger makes essentially this argument. *See* Hamburger, *supra* note 2, at 324–26.

culture that might contribute to lapses in ethical judgment by researchers on federally funded projects.

The opacity of the *League of Women Voters* decision makes it difficult to predict whether the possible spillover effects from unregulated research would be sufficient to justify requiring institutions receiving federal research funds to apply either IRB requirements or some other ethical principle to research not receiving federal funds.[287] The government in that case argued the ban on editorializing was to protect noncommercial educational broadcasting stations from being coerced by the federal financing into being a vehicle for government propagandizing and to keep these stations from being captured by private interests who would use them to express their own partisan viewpoints.[288] In addition, it argued that the ban was intended to prevent taxpayer money from being used to express views with which they disagreed.[289] The Court found that the interest in protecting the stations from government coercion and private partisan capture was "not substantially advanced by" the ban.[290] With respect to the taxpayer disagreement argument, the Court found the ban "so unrelated" to this asserted interest as to make it "not substantial."[291] In addition, the Court noted legislative history suggesting that the ban was motivated in part to "prevent[] the possibility that these stations would criticize Government officials."[292]

These findings suggest that, consistent with the two major concerns that pervade the case law in the area, the constitutional defect in *League of Women Voters* was lack of germaneness and the targeting of ideas. If this were the extent of the Court's rationale, the condition requiring the institution to adopt an "ethical principle" for nonfederally funded research would most likely be valid. In addition, however, the Court explained that the ban could not be conceptualized as a mere "refus[al] to subsidize"[293] editorializing by noncommercial educational stations analogous to the refusal to subsidize lobbying activities upheld in *Regan v. Taxation with Representation*. The Court pointed out that unlike the charitable organization in *Taxation with Representation*, which could form an affiliate to carry on its lobbying

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[287] Making any assessment of *League of Women Voters'* impact on conditional funding doctrine difficult is that only three paragraphs of the lengthy majority opinion are devoted to spending issues. *See League of Women Voters*, 468 U.S. at 399–401. Because the government belatedly raised the funding issue, almost all of the majority opinion is devoted to analyzing the constitutionality of the ban as if it were directly imposed by law. *See id.* at 399.

[288] *Id*. at 384–85.

[289] *Id*. at 385 n.16.

[290] *Id*. at 388.

[291] *Id*. at 385 n.16. Although these findings are obviously relevant to whether these asserted interests are germane to the funding condition, the Court is here analyzing the ban as an outright prohibition, not as a funding condition. *See supra* note 287.

[292] *League of Women Voters*, 468 U.S. at 387 n.18.

[293] *Id*. at 399–400.

activities, the stations are "barred from using even wholly private funds to finance its editorial activity."[294]

It is impossible to determine from the Court's cursory discussion whether the concern here is again merely a specification of the germaneness requirement or whether it adds a new criterion to the unconstitutional spending analysis. Thus, one explanation could be that the condition was invalid because the ban on the use of even *private* funds for editorializing was not germane to the government's primary interest in assuring that the government did not use *federal* funding to coerce stations into being a mouthpiece for government propaganda.[295] On this view, because the condition that institutions adopt an ethical principle applicable to nonfederally funded research is germane to assuring that ethical standards are observed in federally funded research, this condition would likely stand.

Alternatively, the Court's concern in *League of Women Voters* could be that in insisting on a total ban on editorializing regardless of the source of the funding for that activity and irrespective of the percentage of the stations' operating budget the federal funds provide, Congress was simply demanding too much for too little and thus was burdening without sufficient justification a form of expression that the Court had earlier in the opinion characterized as lying "at the heart of First Amendment protection."[296] On this view, the constitutionality of the imposition of the ethical principle requirement on nonfederally funded research is more problematic. The validity of the ethical standards provision would then depend on an assessment of the burden that adoption of the ethical principle would place on the First Amendment interests at stake. If, contrary to my analysis in Parts I and II, the Court were to find that the application of IRB requlations, including the ethical principle requirement for nonfederally funded research, burden a core First Amendment right similar to the restrictions on core political speech at issue in *Spieser* and *League of Women Voters*, it might well hold this provision unconstitutional.[297]

[294] *Id*. at 400.

[295] This is basically the view taken by Professor Sullivan. *See* Sullivan *supra* note 254, at 1465–66. A somewhat different nexus problem would seem to exist with the private capture rationale, for it is difficult to comprehend a connection between federal funding and private capture. It is probably for this reason that Justice Rehnquist (as he then was) did not rely on either of these rationales but instead rested his argument in favor of the validity of the condition entirely on the taxpayer disagreement justification. *See League of Women Voters*, 468 U.S. at 402–08 (Rehnquist, J., dissenting). The Court, in contrast, found this rationale extremely weak or perhaps even impermissible. *Id*. at 385 n.16.

[296] *League of Women Voters*, 468 U.S. at 381.

[297] Unlike the germaneness criterion, this analysis need not lead to an all or nothing result. Under this analysis, the requirement that an ethical principle be applied to nonfederally funded research might be valid except to the extent that it burdens arguably core free speech activity such as interviewing people on matters of public concern.

B. Inducing Unconstitutional Activities

Even if the IRB conditions attached to receipt of federal research funds do not constitute a "penalty" on First Amendment rights under the *Speiser* line of cases, these conditions would nevertheless be unconstitutional if they "induce" the institutions receiving the funds to "engage in activities that would themselves be unconstitutional."[298] The pertinent inquiry here is "whether the condition that Congress requires 'would . . . be unconstitutional' if performed by the [research institution] itself."[299] In answering this question it is important to bear in mind that government generally has greater leeway to restrict constitutional rights when it acts as employer than as sovereign.[300] Thus, even if imposition of IRB restrictions by general legislation would violate the free speech or substantive due process rights of the researchers,[301] state research institutions such as state universities might in their capacity as employers be able to impose these same restrictions through an internal policy decision without violating the rights of their employees.[302]

The analysis in Parts I to III revealed that even if imposed directly by force of law, IRB regulations would be constitutional in most of their applications. The one application that raised serious First Amendment concerns is to social science research using only traditional interviewing techniques, particularly if the research is on a matter of public concern. In coming to this conclusion, I posited someone who wanted to interview people on their attitudes on such matters as abortion and homosexuality but was forbidden by law from doing so without prior approval of an IRB. To complete the

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[298] United States v. Am. Library Ass'n, 539 U.S. 194, 203 (2003) (plurality opinion) (quoting South Dakota v. Dole, 483 U.S. 203, 206 (1987)).

[299] *Id*. at 203 n.2 (quoting *Dole*, 483 U.S. at 210 (omission in original)). Of course a private research institution, including a private university, cannot "itself" violate the First Amendment. *See* Blum v. Yaretsky, 457 U.S. 991, 1002 (1982) ("[The Fourteenth] 'Amendment erects no shield against merely private conduct, however discriminatory or wrongful.'") (quoting Shelley v. Kraemer, 224 U.S. 1, 13 (1948))). There is thus some question whether this branch of the unconstitutional conditions doctrine has any applicability to conditions on receipt of funds by private entities. However, private conduct impelled by government has correctly been held to satisfy the "state action" requirement. *See id.* at 1004–05; Adickes v. S.H. Kress & Co., 398 U.S. 144, 170–71 (1970) (stating that "a State is responsible for the discriminatory act of a private party when the State, by its law [or custom having the force of law], has compelled the act"). The better view, therefore, is that the doctrine should apply to inducement of private as well as governmental actors. In any event, this doctrine is applicable to the numerous state universities receiving federal research funds conditioned on fulfilling the IRB requirements.

[300] *See, e.g.*, Garcetti v. Ceballos, 126 S. Ct. 1951, 1958 (2006) ("[T]he government as employer indeed has far broader powers than does the government as sovereign[.]" (quoting Waters v. Churchill, 511 U.S. 661, 671 (1994))); Connick v. Myers, 461 U.S. 138 (1983).

[301] It is an open question whether government institutions, such as state universities, have First Amendment rights. *See Am. Library Ass'n*, 539 U.S. at 210–11 (plurality opinion). But in any event, private universities possess these rights.

[302] Furthermore, if the concept of academic freedom restricts government from imposing restrictions on universities, this consideration is no longer present when the university itself imposes the restriction.

constitutional analysis, let's now consider the same restrictions imposed not by general legislation but by a policy adopted by a state-run research institution. The key question thus becomes: Would an institutional policy requiring a social scientist to obtain prior approval before conducting such an interview violate the First Amendment right of this researcher?

Although there are no Supreme Court cases directly on point, the leeway that the Court has allowed employers in restricting workplace speech suggests that the Court might well reject a claim by a such a researcher challenging a prior review policy adopted by a state university as a matter of academic policy, even if it would strike down the same restriction imposed on researchers by a general law. Indeed, the core precept of academic freedom protecting the right of institutions of higher learning to define their own mission would be implicated if the university were *not* allowed to place a premium on protecting the interests of research subjects by adopt such a ban.[303] It might be argued nonetheless that requiring researchers interested in documenting public opinion on contentious public policy matters to obtain prior approval and to demonstrate that the benefits of the research outweighs its risks unduly burdens their right to engage in the public debate on these matters. While these researchers undoubtedly have a First Amendment right in their capacity as private citizens to express their views on matters of public concern, it is doubtful that they have any such right to do so in their capacity as university employees.

A more substantial objection is that the greater authority that government may have as an employer (and, in this case, as educator as well) rather than as sovereign to impose regulations on researchers to protect human subjects in no way mitigates the impediment to what is arguably an important medium of democratic self-governance resulting from application of IRB regulations to social science interviews. If we focus narrowly on the inquiry at hand—whether a state research institution can constitutionally impose this requirement on this type of social science research—this argument is unpersuasive. Unlike a federal law requiring all research institutions to apply IRB procedures even to social science interviews on matters of public concern, an individual research institution imposing such a requirement on itself is likely to have little impact on this medium. But this inquiry is in reality not just about the constitutionality of a single campus policy. Rather, it is the last step of an analysis of the constitutionality of a set of federal regulations that in fact apply to almost every research institution in the nation. In this context, then, the conclusion that the individual institution could constitutionally impose these restrictions on its employees means that that the federal government might be able to constitutionally impose these restrictions on every social scientist in the country employed by research institutions receiving federal research funds. Thus while a me-

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[303] *See* Grutter v. Bollinger, 539 U.S. 306, 329 (2003) (recognizing "a constitutional dimension, grounded in the First Amendment, of educational autonomy").

chanical application of this branch of the unconstitutional conditions jurisprudence suggests that the condition is valid, the potential impact of upholding this condition on an important medium of democratic discourse would make this issue more difficult.

In summary, though far from certain with respect to the regulation of nonfederally funded projects and application to research involving traditional interviewing techniques, the case law suggests that the imposition of IRB regulations as a condition of federal funding may be constitutional. If this is so, then most of the constitutional problems that would exist with directly imposing these regulations by force of law are avoided by the conditional nature of the regulations.[304]

CONCLUSION

Innovative research at academic institutions in the United States is critical both to the continued material success of this country and to the health and welfare of its populous. But as important as this activity may be, and though its overregulation may have negative consequences for us all, restrictions imposed on it by IRB regulations do not for the most part implicate, let alone infringe, individual rights secured by the Constitution. Most biomedical research does not involve significant communicative elements, while most of the expressive elements in social science research are arguably no more constitutionally significant than analogously facilitative elements of biomedical research. The best argument for extending First Amendment protection to some aspects of social science research is that traditional interviewing techniques constitute an essential medium of public discourse. But even under this conception, it is not so much the individual right of the researcher that is implicated by the IRB regulations as is a vital democratic structural concern.

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[304] An application of IRB regulation that would likely not be saved by the conditional nature of these regulations would be an IRB decision that engaged in ideological viewpoint discrimination forbidden by the First Amendment. *See supra* text accompanying notes 203–207. Although the state has greater leeway when acting as educator and employer to regulate speech than it does as sovereign, this leeway probably does not include the ability to engage in ideological viewpoint discrimination. *See* Doe v. Univ. of Mich., 721 F. Supp. 852, 863 (E.D. Mich. 1989) (explaining, in striking down a "campus code" applied to controversial classroom speech, that a university may not adopt "an anti-discrimination policy which had the effect of prohibiting certain speech because it disagreed with ideas or messages sought to be conveyed"); *see also* James Weinstein, *A Constitutional Roadmap to the Regulation of Campus Hate Speech*, 38 WAYNE L. REV. 163 (1991). *See generally* Rosenberger v. Rector & Visitor of Univ. of Va., 515 U.S. 819, 830 (1995) (stating that, in regulating speech in a limited public forum, university may engage in content discrimination "if it preserves the purposes of that limited forum," but not "viewpoint discrimination, which is presumed impermissible when directed against speech otherwise within the forum's limitations"); Cornelius v. NAACP Legal Def. & Educ. Fund, 473 U.S. 788, 806 (1985) ("Control over access to a nonpublic forum can be based on subject matter and speaker identity so long as the distinctions drawn are reasonable in light of the purpose served by the forum and are viewpoint neutral.").

A right to research as a species of some larger right of thought and inquiry is better grounded as an individual right. But once this asserted right involves more than pure thought and partakes of conduct that can endanger others, the government's power to regulate this activity cannot be denied or even greatly restricted. As a theoretical matter, the right of thought and inquiry might justify a limited judicial role in invalidating extremely burdensome but weakly justified restrictions on research, including some of the more outrageous IRB decisions reported in the literature. But for a host of practical reasons, including the perils inherent in a fundamental rights jurisprudence not firmly grounded in constitutional text, the Supreme Court is not likely to recognize a right to substantive due process right to research.

Not every social problem, even one as important as overregulation of academic research, presents a problem fit for judicial resolution. Because individual rights in our system are "trumps" on usual social welfare concerns,[305] the judiciary may legitimately ignore the will of the majority expressed in legislation where individual constitutional rights are truly imperiled. But where competing policy concerns rather than individual rights are at stake, as is largely the case with IRB regulation, the matter is more appropriately left to resolution by the ordinary political process.

[305] *See* DWORKIN, *supra* note 101, at xi.