IRB LICENSING
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The licensing of speech or the press is widely assumed to be an obsolete problem. Back in the dimly lit past, the Inquisition and the Star Chamber licensed the press and thereby suppressed much scientific and political inquiry. By contrast, in the enlightened present, such licensing apparently is no longer a significant threat.

The licensing of speech and the press, however, has returned on a wider scale than anything imagined by the Inquisition or the Star Chamber. In response to anxieties about the academic study of human beings, Health and Human Services (“HHS”) has led the federal government in imposing licensing of speech and the press on “human-subjects research.” The government carries out this licensing through Institutional Review Boards—what are known as “IRBs.” Although not familiar to the general public, these boards exist at all universities and most other research institutions, and they license and suppress much talking, reading, analyzing, printing, and publishing.

As it happens, the government also relies on IRBs in more specialized ways—for example, to review new drug and device trials under the auspices of the Food and Drug Administration (“FDA”). The specialized use of IRBs under FDA regulations, however, is not at issue here. Instead, this essay concerns the use of IRBs under the laws and regulations that generally govern human-subjects research—what for convenience are here called the “IRB laws.”

These laws are unconstitutional on many grounds, but the central problem is that they impose licensing of speech and the press. Indeed, the IRB laws are the most widespread and systematic assault on the freedom of speech and the press in the nation’s history.

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2Equally serious is suppression of churches and other tax-free organizations under I.R.C. §501(c)(3), but the suppression under the IRB laws is more far reaching and systematic. McCarthyism was more overtly political, but the IRB licensing is far more pervasive and methodical, and its consequences are far more lethal.
I. LICENSING

The First Amendment’s speech clauses prohibit nothing as clearly or emphatically as licensing. But licensing no longer occupies a prominent place in academic theory or judicial doctrine. It therefore is essential to begin by understanding licensing and why the prohibition of it is so fundamental.

What is Licensing of Speech or the Press? -- Licensing is a requirement that one get permission. Thus, when the First Amendment prohibits Congress from licensing speech or the press, it bars Congress from requiring one to get permission for speaking or publishing.

This licensing of speech and the press is very different from a driver’s license. Before driving, you need a license. Imagine, however, the same for speaking or publishing— that you needed permission from government to be qualified to speak or publish. This would be bad enough and clearly would be unconstitutional, but licensing of speech and the press usually goes further. Imagine that you also needed permission each time you spoke or published. At least, after you get a driver’s license, you can drive where you please. Suppose, however, that you needed prior permission not merely initially, but every time you talked to someone or published an article. You would need permission to begin a conversation, to ask each question, and to publish the answer.

Socrates & Galileo. -- Nothing better illustrates the distinctive character of licensing than the different treatment of the two greatest victims of suppression. The one was punished after the fact; the other was licensed.

Socrates spent his life testing an hypothesis stated by the oracle at Delphi. The oracle declared that no one was wiser than Socrates. But rather than accept this as true, Socrates set about to prove it wrong by questioning his contemporaries. His efforts were a sort of empirical inquiry, to test an hypothesis about himself and, by extension, human nature.

Socrates, in other words, used his interlocutors as “human subjects.” As he understood, questions that cut deep necessarily cause discomfort, and the deeper the question, the greater the discomfort. The advantage is that, by causing internal distress and external shame, such inquiries can force a person to reevaluate herself and, indeed, can educate an entire society. Socrates therefore went out of his way to show up the intellectual and moral failings of his subjects.

On account of his inquiries, Socrates was punished by the demos. Had he put the questions to himself, he would have been left alone. But he posed his questions to others— to his human subjects— and he thereby seemed to call into doubt the gods of the city. In modern terms, he questioned national pieties. Socrates therefore was prosecuted before a jury and condemned to drink hemlock.
But he at least was punished only after the fact, not beforehand. He was not asked to get a license, to get permission, before asking questions. And his student Plato was able to publish the resulting dialogues without getting permission. Although Socrates probably would have much to say about the licensing of speech and press, he himself did not experience it.

In contrast, Galileo was subjected to licensing. Whereas Socrates was able to ask questions and share his views before being censored, Galileo needed to get permission before publication. After Galileo developed proof that the Earth revolved around the sun, Cardinal Bellarmine warned Galileo that his work was unsuitable for publication. But of course Galileo wanted to publish. And he knew that he first needed a license. So in 1632 he quietly obtained a license from a cleric who did not know of the prior warning. Although Galileo thereby got past the licensing system, the Inquisition was not amused. It could not proceed against him for failing to get a license, but it imprisoned him for failing to make adequate disclosure to the licenser.

This method of control, licensing, was what inspired eighteenth-century Americans to seek constitutional protection for the freedom of speech and the press. Of course, Americans were familiar with after-the-fact punishments, whether those experienced by Socrates or more recent victims. But licensing—the prior permission required by the Inquisition and the Star Chamber—seemed more dangerous. Therefore, when Americans in the First Amendment guaranteed the freedom of speech and the press, they most clearly and emphatically secured a freedom from licensing.3

An Invariably Dangerous Method

—Licensing is a consistently dangerous method of controlling speech or the press. It therefore is consistently forbidden.

It is commonly assumed that licensing is not distinctively worrisome. Certainly, in some instances, after-the-fact constraints can be just as dangerous as licensing. But that is not the point. The special danger from licensing is that it is invariably dangerous.

Most after-the-fact constraints on the freedom of speech or the press are not particularly troubling. Indeed, many such constraints are valuable and lawful, as evident from tort, contract, and copyright law. In contrast, licensing is always a dangerous method of controlling speech and the press. Traditionally, therefore, at least as to verbal expression (the expression done through words), licensing was flatly unconstitutional.4

3For the way in which Americans understood the extent of their freedom from after-the-fact constraints, see Philip Hamburger, “Natural Rights, Natural Law, and American Constitutions,” 102 Yale Law Journal 907 (1993).

4The word “verbal” is used here to signify not merely oral expression, but all expression through words, including what in effect are words, such as numbers and symbols in mathematical and computer languages. Of course, the traditional bar against licensing was unqualified only as to civilian constraints, not as to licensing in the military or in the provision of government services, such as the post office.
Licensing is consistently dangerous for several reasons. First, it is a means of wholesale suppression. The government ordinarily must enforce laws against speech in retail fashion, proving the danger of each publication, one by one, in a complex court proceeding. In its licensing, however, the government generally bars publications until they get permission, and it thereby suppresses them wholesale, without individual proceedings and other due process in court. Second, licensing in any sphere of speech is profoundly overbroad and disproportionate. In order to prevent harm in some instances, it imposes prior review in all instances, and it thereby suppresses or at least chills much entirely innocent speech. Most seriously, third, licensing requires individuals to get permission from the government before they speak or publish—as if they had no authority on their own to share information and ideas. Licensing in this manner forces the people to be submissive about their words. It makes them acknowledge the government’s sovereignty over the very means by which they hold the government to account, and it thereby inverts the relationship of individuals to their government.

Being an inherently dangerous method of control, licensing is forbidden without regard to content. The Supreme Court’s doctrine on content discrimination and political speech has led many scholars to assume that the First Amendment protects speech only on the basis of its content. And this makes sense for modes of control, such as injunctions or after-the-fact constraints, that are not inherently dangerous. But licensing is a predictably dangerous method of controlling speech, and because the method is so dangerous, the content of the licensed speech becomes less important. For centuries, therefore, it has been recognized that, quite apart from content, licensing as a method of controlling speech is prohibited.

The last time this sort of censorship flourished in common law jurisdictions was in the seventeenth century. Back then, if you wrote a book, you needed a license or permission before you could print or publish. Just as the Inquisition imposed this licensing in Italy, the Star Chamber required it in England. Even if you merely wanted to speak, you might need a license—as when acting companies in Shakespeare’s time needed a license before they could recite plays on stage.

Such is the censorship that has come back to life. It usually is assumed that licensing came to an end when Parliament abandoned it in 1695 and especially when the First Amendment barred it in 1791. During the past four decades, however, it has returned. As a result, many individuals again need permission for the mere use of language.

II. THE STRUCTURE OF IRB LICENSING

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5The licensing of speech in plays was revived for a while in eighteenth-century England after 1737.
The government imposes the contemporary licensing system through an elaborate administrative hierarchy, structured in four levels. At each stage, the IRB laws revive seventeenth-century licensing of speech and the press.

The Government. -- At the top of the hierarchy is the federal government, especially HHS. The government worries that research on human beings will harm them, and it therefore relies on IRBs, as overseen by HHS, to license such research. Rather than directly carry out the licensing, the government requires universities and other research institutions to do it. In a free society, it is difficult for government itself to impose licensing of speech and the press. This is why the Star Chamber long ago required universities to impose its licensing and why, again today, the federal government makes the universities carry out its newer version.

Like prior governments that imposed licensing, the federal government assumes it is acting on elevated, even benevolent principles, and it sets out its principles for the licensing in a document known as “the Belmont Report.” The government then provides more detailed standards for the licensing in a regulation known as the “Common Rule”—so called because many government departments or agencies have adopted it. The government also authorizes individual IRBs to add their own, local requirements. The result is a federal baseline for the licensing, and federal authorization for more severe local standards, which vary from IRB to IRB, at their discretion.

The government forces universities and other research institutions to impose IRBs in three ways—most prominently through conditions on research grants. The government, primarily HHS, requires all research funds for individuals to run through universities or other research institutions, thus giving the government an institutional means of control. In order for a professor to get HHS research funds, his university first must assure HHS that all human-subjects research at the institution will comply with the principles of the Belmont Report (or some equivalent document), including the underlying principle that all human-subjects research requires a prior license. The university also must assure the government that it will impose the licensing of federally-funded research in compliance with the standards of the Common Rule.

HHS and the other agencies, however, are interested in regulating not merely federally-funded research, but all human-subjects research, and they therefore use their conditions to impose the licensing on all such research regardless of its source of funding. They do this most generally by requiring each institution receiving federal research funding to commit that “all of its activities related to human subjects research, regardless of the source of support,” will be guided by the Belmont or equivalent

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6In theory a university can commit to other principles, if approved by the government, but there is no evidence that any other principles have ever received government approval.
principles. In addition, the agencies invite the institutions to commit themselves to apply the Common Rule to all human-subjects research done by their personnel—that is, not only to federally-funded human-subjects research but also to other human-subjects research. Although this commitment is said to be voluntary, it has not always been so in practice, and most institutions assume that they are obliged to impose IRB licensing for all human-subjects research, whatever the source of funding.

Second, the federal government relies on state negligence law. The government, beginning in the 1970s, understood that if it used its conditions to make the licensing pervasive, it could eventually establish the licensing as the standard of care for research. In other words, it used its unconstitutional conditions to inculcate the understanding that a research institution would be violating its duty of care if it failed to impose the licensing. Institutions therefore feel obliged not merely by federal pressures, but more concretely by state tort law, to apply the licensing to all research conducted by their personnel, even when the research is not federally-funded. As a result, state negligence law, or at least the fear of it, has these days become the primary force behind the licensing.

To top it off, many states add a third mode of coercion. They adopt statutes requiring the use of IRBs. These statutes vary, and some are sweeping. For example, some impose IRBs not merely on the personnel of research institutions, but on the general public.8

One way or another, the licensing comes with the force of law. Federal law sets the standards for the licensing and uses conditions to establish an initial layer of coercion. Then state tort doctrine and special statutes add more direct coercion.

The Universities. --At the next level of the hierarchy are universities and other research institutions. They uniformly comply with the government’s demands.

Most basically, they establish IRBs and require all faculty and students to comply with the IRB licensing. They also typically hire staff to help enforce the licensing—for example, to help track down violators. Recently, many universities have even established entire administrative branches, headed by a provost or vice-president of research, to give force to IRB demands.

Having established IRBs and their associated bureaucracies, how do universities induce faculty and students to submit? Some universities euphemistically threaten “serious consequences”; others speak more bluntly of dismissal or expulsion. Either way, universities rarely have to resort to such measures, as IRBs rely on their own power to enforce the licensing.

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7 Federalwide Assurance (FWA) for the Protection of Human Subjects, OMB No. 0990-0278 (approved for use through June 30, 2014).
8 See, e.g., Code of Virginia, § 32.1-162.19.
IRBs. The IRBs consist of faculty, administrators, and at least one community member, all of whom are to be chosen for their “sensitivity to . . . community attitudes.”\textsuperscript{9} Like the Inquisition, they act in secret, and they welcome anonymous denunciations. Like the Inquisition, moreover, they combine all legal functions: They regulate and license speech, they accuse violators, and they judge, and punish them. And to protect their secrecy and discretion, they allow no appeals. In short, they provide the very opposite of due process and separation of powers.

The most common activity of IRBs is to license speech and the press, both in the getting of information and the sharing of it. When a faculty member or student seeks to do research on human subjects, she must prepare a research proposal and submit it to the IRB at her institution. The IRB then will review the proposal and follow one of several options: It will permit her work, deny permission, or most typically deny permission until she agrees to make changes—changes that usually limit her acquisition or sharing of information.

In particular, the IRB can interfere with her use of words. It can forbid her from talking to human subjects, reading about them, observing and taking notes about them, or publishing about them. It can do this even if she merely wants to interview government officials, distribute social science surveys, or read public records (such as court documents and public census data). The IRB also can directly modify her research: It can rewrite her questions, adjust her academic method, or otherwise alter her inquiry. And of course the IRB can limit what she may publish. The Inquisition inked-over or rewrote passages in book manuscripts, and IRBs similarly limit what academics publish in their articles and books.

Almost always, IRBs direct how one can initiate conversation or otherwise interact with other people. They do this through their regulation of “informed consent,” which sounds innocuously like medical informed consent, but which actually is an additional layer of licensing. Indeed, IRBs usually insert their limits on speech and publication in the informed consent documents, thus presenting their coercive censorship as if it were simply a matter of getting consent.

An IRB will at best give a scholar a Hobson’s choice. He must promise not to learn the identity of the persons from whom, or about whom, he gets information. Or he must promise not publish the identity of such persons. And this is merely the formal choice. The IRB often will skew the choice toward limiting the acquisition of information where it does not fully trust the researcher to refrain from revealing what he knows—the point being that what a researcher does not know, he cannot publish. Even more pervasively, IRBs often delay approval, or hold out the threat of delay, to get scholars to self-censor, this being part of what the Supreme Court calls a “chilling effect.”

\textsuperscript{9}45 C.F.R. §46.107(a).
The suppression of speech and the press by IRBs even goes far beyond what is conventionally understood as licensing of speech and the press. For example, IRBs often require the destruction of data. When scholars publish, they have a moral and academic duty to preserve their data—so that the accuracy of their conclusions can be tested. When scholars don’t preserve data, one might reasonably suspect fraud. Nonetheless, IRBs require scholars to disaggregate and otherwise destroy their data—whether by requiring that “identifiers” be separated from other information or by requiring scholars to destroy all of their data, usually after three years. Either way, such destruction means that many studies can never be challenged for fraud or even merely for misunderstanding the data.

As if this were not enough, some IRBs order scholars and students to stop analyzing data—as when the University of Michigan warns that, without IRB permission, “no identifiable data may be . . . analyzed.”[10] In other words, IRBs not only license the acquisition and publication of information; they not only require the destruction of knowledge; they also bar thinking. Even the Inquisition did not do this.

Individuals. --At the bottom of the system are the scholars and students who hope to learn and publish. One might be forgiven for forgetting them, for they really are at the bottom of the pile.

They face two layers of licensing. First, already in the course of their inquiries, researchers must get permission before talking, writing, distributing printed materials, or even merely reading. Second, at the same time that they get permission for talking, etc. in their inquiries, they also must get permission for what they ultimately will publish.

Faculty and students face devastating punishments for nonconformity—most pervasively because, if an individual fails to comply, his IRBs will identify him as “uncooperative” and will review his future work with greater severity. Thus, the greatest weapon for getting researchers to submit to the licensing is the power of IRBs to deny researchers permission for their later inquiry and publication. In other words, the licensing serves a double function. The current licensing is the means of dictating what can be said and published and what cannot. At the same time, the threat of future licensing is the means of enforcing the current licensing.

If a scholar begins inquiry or prepares a paper for publication without permission, the IRB can tell him to stop. If he submits such a paper to a journal, the IRB can demand that he withdraw it.[11] Indeed, IRBs increasingly compare faculty publications with IRB records, to ferret out which scholars failed to get permission.

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IRBs even can declare a scholar unfit to do any future research, and they sometimes cooperate to suppress scholarship or harass scholars into quitting.\textsuperscript{12} Faculty and students therefore often retreat from inquiry and publication that might annoy their IRB. As a result, entire areas of scholarship have declined, and much important inquiry is never even begun, let alone published.

This is a standard complaint among scholars. For example, a distinguished scholar of journalism, Margaret Blanchard, abandoned her work on contemporary topics. She explains: “I am . . . leaving the contemporary period behind. It is much safer in the nineteenth century.” Only living persons are “human subjects,” and therefore “you do not have to worry about the IRB when you work in the nineteenth century.” Blanchard adds: “I have seen students alter research projects to avoid IRB contact. I have seen some give up projects because of the red tape involved. I have heard words such as ‘thought control’ used far too often.” She concludes: “A better formula for stultifying research is beyond contemplation.”\textsuperscript{13}

Academics even are afraid to complain openly about the licensing. They privately mutter about IRBs, but they are too fearful to speak up, lest their IRB limit their future work. A journalist who wrote about IRBs found that “everyone” he talked to (except one whose case was already public) “requested anonymity.” The faculty members wanted anonymity because they were “afraid of their IRB,” and “the IRB members all requested anonymity” because they were “afraid of the federal regulators.”\textsuperscript{14} The licensing system thus stifles not only academic inquiry and publication but also complaints about its suppression of speech.

Such is the modern licensing system--all four layers of it. As in past, the government demands licensing; the universities do the government’s bidding; the licensers deny permission to speak or publish; individuals suffer. The seventeenth century has come back to life.

III. THE UNCONSTITUTIONALITY OF THE IRB LAWS

In imposing licensing of speech and the press, the IRB laws--the statutes and regulations on human-subjects research--revert to the past in a way that has

\textsuperscript{12}For example, after a member of one of the University of Michigan IRBs wrote a secret memorandum denouncing Professor Guyer, it was acquired by the University of Washington, which then used it against Guyer’s co-author, Professor Loftus. The University of Washington prevented her from pursuing their research and publication, which led to her departure for the University of California, Irvine. Carol Tavris, “The Cost of Courage,” in Maryanne Garry, Harlene Hayne, Do Justice and Let the Sky Fall: Elizabeth F. Loftus and Her Contributions to Science, Law, and Academic Freedom 207 (Lawrence: Erlbaum Associates, 2007).

\textsuperscript{13}“Should All Disciplines be subject to the Common Rule?,” Academe, May-June, 2002, at 62, 68 (comments of Margaret Blanchard).

\textsuperscript{14}Cary Nelson, “Can E.T. Phone Home? The Brave New World of University Surveillance,” Academe, 30, 35 (Sept.-Oct. 2003). The exception was David Wright, whose case had become notorious. Id.
They return to the sort of control developed by the Inquisition and the Star Chamber, and they thereby clearly are unconstitutional.

The constitutional point rests on both federal and state law. At the federal level, the First Amendment provides that “Congress shall make no law . . . abridging the freedom of speech, or of the press.” This clause, moreover, is understood, under the Fourteenth Amendment, to limit the states. Last but not least, state constitutions contain their own speech and press clauses. Although the argument here is framed in terms of the First Amendment, the reasoning obviously also extends to the state guarantees.

Force of Law. --To begin with, the licensing system is imposed by force of law. Although the system sometimes is excused as voluntary, government force is apparent in three ways.

First, the federal government requires the use of IRBs as a condition of its research grants. This mode of coercion raises complex constitutional issues; yet even under current doctrine the conditions are clearly unconstitutional. The conditions apply not only to federally-funded research but also, at most universities, to privately-funded research. In other words, the government leverages its grants to a relatively small number of professors so as to control the speech of all professors and students, and this shows that the conditions are profoundly disproportionate and not at all germane. Indeed, licensing of speech by its nature is disproportionate, for in order to prevent harm in some instances, it imposes prior review in all instances, and it thereby inevitably suppresses and chills much speech that is harmless. Thus, even as to federally funded research, the IRB licensing is always disproportionate and is an unconstitutional condition.15

Second, as already noted, state negligence law is understood to require the use of IRBs as part of a university’s duty of care. Although the federal government initially relied on its conditions to impose the licensing, it increasingly has shifted weight to negligence law. By the beginning of the twenty-first century, negligence law was enough to get universities to impose IRBs on all of their personnel, whatever the source of funding. It even was enough to get universities to impose IRBs in conformity with the standards of the Common Rule and federal guidance. Thus, although some

15More generally, the consent to the conditions cannot justify them. The Constitution is a legal limit imposed by the people as a whole. The federal government therefore can go beyond this limit only with the consent of the people as a body, not merely with the consent of the states, private institutions, or private individuals. The First Amendment, for example, is a legal limit on government adopted by the people, and as a result, no amount of private consent can give the government the power that the people, in the Amendment, denied to it. Put simply, private contract cannot enlarge federal power.

Nor can the consent to the IRB conditions preclude the possibility of federal force, for even with consent, there always can be force in the inducement or in the implementation. The conditions imposing IRBs allow the government to go to court to recover its funding from institutions that fail to comply with the conditions, and the conditions thereby are backed by the force of law. For further details of these arguments, see Philip Hamburger, “Unconstitutional Conditions: The Irrelevance of Consent,” 98 Virginia Law Review, 479 (2012).
universities opt out of the conditions requiring application of the Common Rule to non-federally-funded research, these universities, in response to negligence law, usually apply the Common Rule to all human-subjects research.

The third layer of coercion comes from the state statutes that directly require IRBs. Some of these statutes come into play only in the absence of federal law, but this does not weaken the point. If ever the federal conditions and state negligence law were insufficient, the state statutes would remove any doubt about the government force.

Direct Licensing of Speech. --The central constitutional question is whether the IRB laws license speech. It often is assumed that because the regulations refer to “research,” they concern conduct, but in fact they directly focus on speech.

Incidentally, even if the IRB laws were regulations of conduct, they still would be unconstitutional, for they single out academics and academic inquiry for utterly repressive licensing. This is not the place to parse the constitutional doctrine on expressive conduct; but if flag burning, porn movies, and nude dancing are constitutionally protected, so too is academic research and its publication. There is no need to go down this road, however, for the IRB laws directly license speech in two ways.

What Must Get a License. --First, when specifying what must get a license, the IRB laws focus on speech. The laws begin by requiring licensing for human-subjects research, but they then define this in terms of publication. For example, the Common Rule defines a “human subject” as “a living individual about whom an investigator . . . conducting research obtains (1st) Data through intervention or interaction with the individual, or (2nd) Identifiable private information.”16 The laws thus define a human subject in terms of “data” and “information” and thereby focus not on harm, but on the acquisition and sharing of knowledge.

Going even further in this direction, the Common Rule defines “research” as a “systematic investigation” designed to produce “generalizable knowledge.”17 In the scientific model of research, researchers develop generalizable statements or theories, and these are expected to be published, so they can be tested by other scholars. Following this model, the Common Rule defines research as an attempt to produce

16 45 C.F.R. §102(f).
17 45 C.F.R. §102(d). Indeed, the government requires institutions to acknowledge that “generalizable knowledge” means what is “expressed.” The government asks institutions to commit to “the ethical principles” stated in the Belmont Report, which explains that “the term ‘research’ designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).” In thus echoing the words of the Common Rule, the government and the institutions recognize that the Rule requires licensing of attempts to develop or contribute to knowledge “expressed” in theories or statements. Terms of the Federalwide Assurance for the Protection of Human Subjects, §1, at http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html.
generalizable knowledge, and it thereby requires individuals to submit to the licensing when they seek the sort of knowledge that is publishable.

That this is what the Common Rule does is acknowledged by IRBs. They widely assume they must license not just any research, but that which the researcher “plans to publish” or which is “publishable.” For example, the University of Michigan IRBs state that “publication” is an “indicator” of “generalizable knowledge.”18

The focus on publication is confirmed by the perverse results. Even when an academic engages in dangerous physical interactions, she needs no permission as long as she is not aiming for “generalizable knowledge”—the sort of knowledge that academics consider publishable. But when she pursues entirely harmless activities, she needs permission if she is aiming for what might be publishable. Thus, not only on the formal surface of the regulations, but also in reality, the guiding principle as to what must get a license is publication rather than harm.

In the biomedical sciences, for example, academic doctors do not need permission if their efforts are narrowly to cure their patients, for however dangerous their conduct, it aims merely at particularized knowledge. But the same doctors must get permission as soon as it becomes apparent that they may acquire “generalizable knowledge,” that which may be publishable. Of course, this is exactly the sort of knowledge that has the potential to be applicable to other patients and that therefore needs to be published, so other doctors can test it and improve their treatment of their patients. Under the IRB laws, however, this potential for publication triggers the licensing and suppression.

Similarly, in the humanities and social sciences—for example, in English and politics departments—faculty and students can read, write, and publish about their human subjects without permission, while they seek only particularized knowledge—for example, when writing up their family’s genealogy. But when they seek generalizations and thus publishable conclusions, they must get permission. Thus, what is evident from the definitions in the IRB laws is confirmed by the bizarre results: The laws require licensing not for harmful activity, but rather for attempts to develop publishable knowledge.

**How IRBs Must Conduct the Licensing.** --The second way that the IRB laws focus directly on speech concerns how IRBS must conduct the licensing. The laws require IRBs to review research for its risks, including the risks from what researchers say or publish.

Under the IRB laws (most directly, the Common Rule), IRBs must review and suppress speech already at the inquiry stage when researchers ask questions, distribute printed questionnaires, or otherwise communicate with people. IRBs also must review

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and suppress what they anticipate researchers will say or publish at the next stage, when researchers will present papers, publish articles, or otherwise share their results. The laws thus directly ask IRBs to license speech in both the acquisition and the sharing of information. Even the Inquisition and the Star Chamber licensed words only at the dissemination stage, not in the preceding inquiry.

In defense of IRBs, it sometimes is said that they do not overtly stop much research, but usually only limit what researchers say and publish. But that is exactly the problem. Under the IRB laws, IRBs mostly control various forms of speech, whether talking, writing, printing, or publishing.

The IRB laws thus directly require licensing of speech and the press. They do this, first, in defining what must get a license and, second, in dictating how IRBs should do the licensing. On both grounds, the IRB laws are unconstitutional.

Other First Amendment Violations. --Although the central constitutional difficulty is licensing, the IRB laws present a smorgasbord of First Amendment violations. Indeed, the IRB laws infringe almost every free-speech doctrine.

For starters, the IRB laws penalize academic speech and publication, and they thus engage in content discrimination. The IRB laws also engage in viewpoint discrimination, for they single out the direct study of human beings, in particular the scientific empirical method. That this is viewpoint discrimination becomes especially clear when one considers how empiricism has repeatedly challenged moral and political verities. So emphatic is the targeting of empiricism that many scholars have shifted to theoretical work. Mere theory often is less effectual than empirical study, but it at least avoids the censors.

The IRB laws also run into trouble under the overbreadth doctrine, for when they impose licensing, they inevitably authorize the review and suppression of vast amounts of talking and publication that will never be harmful. The laws allegedly aim at harm, but they suppress the harm by generally subjecting human-subjects research to licensing, and they thereby are grossly overbroad.

The IRB laws, moreover, impose standards that are unconstitutionally vague. The regulations require IRBs to weigh the “risks” and “benefits” of research, including the risks and benefits of publication. In its guidance, HHS acknowledges that these “determinations of risk and benefit” are “subjective.” Rather than worry about the vagueness, however, HHS embraces it as an opportunity. It openly asks IRBs to take into account “prevailing community standards”--what Socrates would recognize as the arbitrary and repressive demands of the demos.19

The National Science Foundation even requires IRBs to license in ways that prevent many of the constitutionally protected benefits of free speech. IRBs are expected to suppress inquiry and publication where it would lead to “legal harm,”

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19OHRP, Institutional Review Board Guidebook, Chapter III, Part A.
“financial harm,” “moral harm,” social “stigma,” mental “upset,” or even mere “worry.”20 These, however, can be among the advantages of research and its publication. For example, I used to study the Ku Klux Klan. Although I worked on the Klan out of intellectual curiosity, and although most of the Klan members I studied were already dead, I would not have been overly dismayed if my research had caused some of them legal and financial harm, or if it had caused them social stigma and worry. Some “risks” are benefits.

In getting IRBs to prevent these risks, HHS and the National Science Foundation impose a sort of Victorian prudishness. Little nowadays is not openly discussed, but HHS cautions IRBs: “Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one’s own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence.”21 In other words, when scholars study addiction, desire, or other aspects of human nature, IRBs should use their censorship to protect individuals from academic questions that might cause them discomfort. And this is about the use of words to acquire information; the censorship is even more stringent when it gets to what scholars can publish. Although the First Amendment (as recognized in Cohen v. California) protects the freedom to offend, the IRB laws stifle entirely civil discussions of serious matters.

The IRB laws thus brazenly violate one First Amendment doctrine after another; and this should not be a surprise, for the licensing of speech lends itself to other First Amendment problems. Licensing, however, is the preeminent constitutional problem. Although details of the First Amendment’s freedom of speech and press are disputed, nothing is more clear than that the Amendment barred licensing of speech or the press. Such licensing traditionally was understood to be the epitome of tyranny, and as evident from the IRB laws it remains a profound danger.

Newspaper Review Boards. --To understand the unconstitutionality of the IRB laws, just imagine an NRB, that is, a Newspaper Review Board. Imagine that the government used conditions and regulations to require not universities, but newspapers to establish review boards. Imagine, moreover, that a journalist had to get permission from an NRB before beginning any investigation designed to produce publishable knowledge.

Of course, publishable knowledge is different for journalists than for academics. Accordingly, whereas the IRB laws focus on “generalizable knowledge,” the NRB laws would focus on “particularizable knowledge.” But all the same, the NRBs would license investigations designed to produce publishable knowledge.

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21 OHRP, Institutional Review Board Guidebook, Chapter III, Part A.
A journalist thus would need permission before beginning any investigation—even before merely reading, observing, talking, or interviewing—if her goal were to get publishable information. When examining her acquisition of information, the NRB would weigh the “benefits” and “risks” of her research, including the risks arising from publication. To limit the risks, it could rewrite her questions, and it certainly would dictate how she could converse or interact with other people, lest she ask insensitive, stressful, or embarrassing questions. As for her sharing of information, the NRB would prevent her from publishing the names of persons who might suffer financial, reputational, or emotional harm, including mere anxiety, as a result of publication. It even would bar her from sharing information with other journalists, unless she got further permission. Last but not least, it would require the de-identification and other destruction of her information, so that her files could not be used later by other journalists.

All of this licensing is outrageously unconstitutional. It is unconstitutional regardless of whether it is required directly or by condition. And if it is unconstitutional for journalists, it also is unconstitutional for academics and students.

IV. ALLEGED JUSTIFICATIONS

Notwithstanding the constitutional difficulties, IRB licensing is commonly said to be warranted by the doctrines of the Supreme Court. Accordingly, it is time to turn to the most concrete of these doctrinal justifications, to see if they really can sustain the licensing.

* Licensing of Conduct?* --Although it has been seen that the IRB laws focus on speech, especially publication, there still may be a lingering concern that research is conduct and that the licensing therefore is justifiable. The First Amendment undoubtedly leaves room for the licensing of conduct, even much expressive conduct, and on such grounds perhaps the IRB laws are lawful. This line of reasoning, however, fails to distinguish between popular perceptions of the targeted conduct and the legal definition of what is suppressed. Certainly, some research includes conduct, and at least some such conduct has the potential to be harmful. Yet the IRB laws define “research” in terms of an attempt to publish rather than in terms of conduct, and they require IRBs to limit what can be published. Therefore, notwithstanding that IRBs do stop some harmful conduct, it is difficult to justify the IRB laws as regulations of harmful conduct. Of course, the government could license harmful conduct, including that done in research, if it adopted laws that focused on this danger, but that is not what the government has done.

The concern about conduct, moreover, fails to distinguish between the licensing of expressive conduct and the licensing of words said in a range of conduct. Although
it is unconstitutional for the law to require licensing of words in general, it also is unlawful for the law to impose such a constraint in a narrow range of circumstances. In this instance, the IRB laws directly require licensing of the speech done in connection with the academic conduct known as “research.” Although the licensing of words is thus confined to what is said and published in pursuit of this conduct, it remains licensing of words. In fact, the linkage to the conduct merely serves to ensure that the law discriminates against the unpopular activity of an unpopular group. Far from justifying the licensing, this focus of the licensing suggests an additional reason why it is unconstitutional.

Ultimately, the government should never be able to mask its licensing of words by tying the words to conduct. For example, although a state can license driving, it cannot license speaking while driving; nor can it license driving on the basis of what will be said while driving; for it still would be licensing speech.¹ If the government could get away with such excuses, it could always get cover for licensing words. In fact, the sixteenth- and seventeenth-century English licensing laws illustrate this danger, for rather than impose licensing on words in general, they imposed licensing on printing—that is, on conduct in the use of a new technology. But the licensers were meant to focus on the words that would be printed, and the English licensing laws thus were a perfect example of what the First Amendment prohibited. To be sure, a flat anti-masking rule could not be sustained for injunctions, after-the-fact constraints, or non-verbal expression. The licensing of words, however, has long been strictly forbidden, and this constitutional freedom would be utterly enfeebled if the government could justify such licensing simply by focusing it on words used within a range of conduct, or on conduct involving words.

Licensing of a Precursor to Publication? --In a variation of the conduct justification, it sometimes is said that when IRBs license research, they suppress only a precursor to publication, not publication itself. On this reasoning, the licensing is not unconstitutional.

The First Amendment, however, does not bar licensing only for formal publication. So narrow a reading of the amendment would give less protection to speech than to the press, and would protect publication while allowing the government to suppress the manuscript words that lead up to publication. In fact, English licensing regulations originally licensed the production of manuscripts, and when (as already noted) they eventually kept pace with technology, they focused on printing rather than publication. Other regulations, moreover, controlled speaking on stage. It thus becomes apparent that when the First Amendment barred licensing, it protected all sorts of words, whether spoken, written, printed, or published.

¹ Because the point here only concerns the licensing of words, there are no implications for the licensing of expressive conduct; nor for after-the-fact penalties (such those on driving while using a phone).
Nonetheless, the IRB licensing controls the words of researchers at all stages of their work, in research, publication, and beyond. It begins by controlling what academics say, write, or print in the course of their research; it then controls what they say when formally presenting or publishing the research; it concludes by barring their transfer of their data. Therefore, even if the First Amendment made a fetish of publication, the IRB licensing is no mere precursor.

The precursor excuse looks especially feeble when one recognizes that much research consists of nothing more than talking, writing, or distributing printed materials. For example, much epidemiological research consists of interviewing; much medical research consists of taking notes; much sociological research consists of sending out printed questionnaires. It therefore is highly misleading to talk about research as a precursor to speech or publication. Already when IRBs license the acquisition of knowledge, they very often are dealing with mere talking, writing, publication.

Even when research consists of more than mere speech, its status as a precursor to publication leads to a very different conclusion than may be assumed. In licensing research (including the research that involves conduct), IRBs mostly limit the acquisition and dissemination of information. In limiting the acquisition of information, moreover, IRBs are mainly concerned about the harm from its dissemination. In other words, IRBs restrict the getting of knowledge chiefly in order to limit the sharing of the knowledge. It will be recalled that what a scholar cannot learn, he cannot publish. The licensing of research is thus the most effective way of controlling its publication.

On several grounds, therefore, the precursor argument obscures the realities. It simply is mistaken to assume that speaking, writing, printing, publishing occur only when scholars disseminate their knowledge in articles and books. All of these things, and the licensing of them, already occur in the acquisition of knowledge.

**Scientific Rather Than Political Speech?** -- Another justification of the IRB laws rests on the political speech doctrine. On the assumption that the First Amendment centrally protects political speech—even perhaps only political opinion—it is supposed that the Amendment does not fully protect the scientific or academic speech licensed by IRBs. Scientific and academic speech, however, is foundational.

The inquiry done by scientists and other academics has long been a central illustration of the importance of freedom of speech and the press. Even before the Athenians forced Socrates to drink hemlock, they condemned Anaxagoras for speculating about the physical character of the sun and the moon. Two millennia later, Galileo revealed not only the arrangement of the heavens but also, much closer to earth, the danger of licensing scientific or other academic publication. The earthly importance of his work was recognized by John Milton in his famous 1644 tract, *Areopagitica, A Speech For The Liberty Of Unlicensed Printing*. Milton recalled that he had visited Galileo in prison and had learned how the licensing had stifled scientific
development in Italy. Ever since, Galileo’s ordeal has been understood as the preeminent illustration of the dangers from licensing.

Early Americans recognized the value of protecting the full range of knowledge from licensing. When the Continental Congress in 1774 explained “[t]he importance of the liberty of the press,” it began by observing the liberty’s significance for “the advancement of truth, science, morality, and arts in general.” An American poem on the freedom praised the breadth of the protected knowledge, including “[p]hilosophic goods,” “works of wit,” “schemes of art,” and other “learning.” Of course, the freedom also had political advantages against “lawless pow[e]r.” Yet its value was not limited to politics. As summarized in the poem, it was both the “Nurse of Arts and Freedom’s Fence.”

In fact, scientific speech—in both inquiry and publication, and in both the hard sciences and the social sciences—is the foundation of modern society. By continually challenging accepted truths, it lays the basis for the society’s wealth, its progressive character, and its politics. In Galileo’s era, the view that the world circled around the sun seemed to turn the universe upside down, thus elevating human beings and their world and overturning the authority that had seemed to run from God and the Church to kings. Today, science similarly threatens accepted assumptions in one field after another, including education, the environment, and medicine—as evident from debates about evolution, climate change, and various drugs.

In short, already in ancient Athens, even more so in seventeenth-century Europe, and especially in contemporary America, political debate rests on scientific debate. Nor should this be a surprise. If politics is to depend on realities rather than illusions, it must arise from accurate foundations. Licensing therefore is at least as dangerous when focused on scientific or academic speech as when aimed at political speech.

Compelling Government Interests. --A final doctrinal justification of the IRB laws rests on claims about compelling government interests. According to the Supreme Court, the freedom of speech is not absolute, and a constraint on speech can be justified by a sufficiently strong government interest.

Undoubtedly, there is a government interest in preventing harms, including those arising from research. But this does not settle the matter, as it has been seen that the IRB laws focus not so much on harm as on speech—indeed, on the full range of talking, reading, writing, printing, and publishing. The constitutional inquiry therefore cannot rest with the generic question of whether there is a compelling government interest in preventing research harms. Instead, the inquiry must concentrate on

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23“On the Freedom of the Press,” Independent Gazetteer (Phila.) (Jan. 4, 1783). In focusing on the freedom from licensing, the poem compared the freedom of the press to an unlicensed tavern and complained about inquisitors.
whether there is a government interest that justifies using the licensing of speech as a means of preventing research harms.

The question of whether there really is a compelling government interest here must await the discussion of harms in Part VI; but even if there were such an interest, it is improbable that it could justify the licensing. Although a compelling government interest can justify after-the-fact penalties, and even can justify the licensing of moving pictures and other expressive conduct, the Supreme Court has never upheld the licensing of words on such grounds. Nor should it. Licensing is a distinctively dangerous method of controlling words, and it therefore was flatly forbidden.

Put more gently, it is difficult to discern how the government can have a compelling interest in the licensing of speech. Government always has a range of options for addressing harms, and thus even if it has a compelling government interest in regulating research harms, this does not mean it has such an interest in relying on a singularly unconstitutional and ill-fitting method of regulation. A compelling government interest can justify much, but not a law that is most dangerous and least narrowly tailored.

Evidently, the doctrinal justifications for IRB laws are very weak, and this can be confirmed by returning to the notion of Newspaper Review Boards. In justifying their licensing of journalistic research, NRBs would claim to be licensing mere conduct and, indeed, a mere precursor to speech; they further would claim to be licensing only empirical speech and publication, not political opinion; they even would claim a compelling government interest in preventing harm. Such justifications, however, would be of no avail. Any law establishing NRB licensing would clearly be unconstitutional, and what is sauce for the NRB goose is sauce for the IRB gander.

V. HOW THE GOVERNMENT GOT INVOLVED IN CENSORSHIP

Although the constitutional logic against the IRB laws is fairly straightforward, there may remain a sense of incredulity. Is it really possible that the government of the United States has adopted the method of controlling speech and the press employed by the Inquisition and the Star Chamber? At first blush this seems unlikely. Why would the government have done this? Indeed, why would HHS--the department devoted to health--have taken the lead in imposing such licensing? And how could the licensing have succeeded in the face of the First Amendment? The improbability of the censorship begs an explanation.

HHS and the Medicalization of Speech Harms. -- An initial hint can be found in the role of HHS. On the face of the matter, it is odd that HHS has led the imposition of the licensing, for much of the licensed research has nothing to do with health. Upon closer inspection, however, it is no coincidence.
An underlying factor was the growing tendency to take a medical view of speech harms. Only a narrow range of harms are legally significant, and this confined conception of harm is essential for a broad vision of free speech. Medically, however, any harm, however slight or ephemeral, can be considered harmful, and this medical attitude found support in the mid-twentieth century in what now is HHS (then the Department of Health, Education, and Welfare). This department thus began to assume that even minor harms from words and inquiry were dangerous in ways that required its solicitude.

Allied with this broad medical vision of harm was a recognition that the scientific understanding of research rests on publication. From the scientific perspective, the goal of research is to develop a theory or statement of general application—the generality being what makes it publishable and what allows it to be tested. HSS therefore had good reason to understand research in terms of “generalizable” or publishable knowledge. Accordingly, when it began to worry about harms in research, including speech harms in research, it assumed it had to focus its regulations on attempts to produce the sort of knowledge that could be generalized or published.

This anxiety about medical harms in research led to licensing because HHS aimed not merely to punish harms, but to prevent them. Most regulation merely punishes harm after it occurs. HSS, however, wanted to prevent what it considered harm, and it therefore turned to licensing to intervene before any harm took place.

On these foundations, already in the 1950s and '60s, HSS imposed an early version of its licensing of speech on the research it funded. Already then there were expectations that all research, even privately-funded research, should be licensed. But it was not until the next decade that an unprecedented crisis made this possible.

The Public Health Service, which was part of HSS, had for decades been studying latent syphilis among black men at Tuskegee. Although initially the study was not necessarily harmful, the Public Health Service did not tell the men about penicillin when it became available after World War II. The drug would have helped at least some of them, but the Service apparently wanted to preserve its opportunity to study untreated men. The Public Health Service’s callous behavior became public in 1972, and the exposure of Tuskegee and the government’s other medical misadventures should have prompted caution about expanding government power over research. The federal health establishment, however, responded in a way that Sigmund Freud would have recognized.

Rather than accept that government medical research was distinctively risky, the government declared that all human-subjects research was risky and that it therefore

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24 Of course, this view of harm was not only medical, but its other foundations, most profoundly its theological foundations, need not be recounted here. For the sake of simplicity, and to recognize the continuity of federal research policy, HEW is referred to here as “HHS.”
needed to be licensed. Through this projection, the government simultaneously
deflected criticism and extended its licensing from federally-funded research to
privately-funded research. The department that had been most responsible for risky
medical research thus came to oversee a vast swath of academic inquiry.

Far from being a conspiracy, this was merely a natural response to the
circumstances. HSS already understood research in terms of publication and already
saw speech harms in research as a medical problem that required licensing. It therefore
did not blanch at licensing the full range of “human-subjects research,” regardless of
whether it involved physical interactions or mere talk, and regardless of whether it was
biological, medical, sociological, political, legal, religious, or literary. No longer a
private matter among consenting adults, speech and publication in research had become
what medically-minded officials considered a health threat, and on this basis it seemed
squarely within HHS’s mission.

The Supreme Court. --Unfortunately, the role of the federal government in
licensing speech does not stop with HHS and the other complicit agencies. Even more
fundamentally, it is necessary to consider the doctrines of the Supreme Court.

Although the First Amendment’s core protection for speech was an unqualified
bar against the licensing of words, the Supreme Court, during the twentieth century,
focused on the Amendment’s protection against a wider range of threats. There is
much to be said for taking a broad view of the freedom of speech, but the Court
protected the periphery in a manner that weakened the core freedom from licensing.

Of particular concern, the Court sometimes defended its expansive vision of
freedom of speech by generalizing about the threats to this freedom as if there were
nothing special about the central danger from licensing. Reenforcing this suggestion
of equivalence, the Court loosely distinguished between “post-publication restraints”
and “pre-publication restraints,” thus blurring the distinction between licensing and
injunctions. The Court, moreover, sometimes suggested that it made little difference
whether restraints came before or after publication. The Court even spoke loosely
about a freedom of expression, as if the licensing of merely verbal speech could be
evaluated in the same way as the licensing of moving pictures and expressive conduct.

This lumping together served a purpose, for it justified the Court’s expansive
vision of freedom of speech, but it probably was not necessary for this end, and it
certainly has come with a cost. The reality is that most injunctions, most after-the-fact
constraints, and even most licensing of expressive conduct are lawful. Accordingly,
when the Court spoke generally about a freedom from these things, it did not mean a
freedom from all injunctions, all after-the-fact constraints, or all expressive conduct,
and it therefore had to develop doctrines explaining the limits of the freedom. For
example, it developed doctrines about content discrimination, political speech,
expressive conduct, and compelling government interests. None of these doctrines
were necessary for understanding the licensing of words, but all of them were essential
for sorting out when there would be protection for expressive conduct or against injunctions and after-the-fact constraints.

Although these doctrines were designed to police the boundaries of the freedom enjoyed at the edges, they were stated so broadly that they cut back on the core freedom from licensing. The doctrines seemed to suggest that licensing—even licensing of merely verbal speech—could be constitutional if it did not focus on political speech, if it did not discriminate on the basis of content, or if it served compelling government interest. Of course, some of the Court’s more sober opinions pointed toward other conclusions, but its primary doctrines, when stated abstractly, practically invited the government to license speech.

The Court undergirded its doctrines limiting speech by intoning that the freedom of speech is not absolute. This certainly is true as to injunctions, after-the-fact constraints, and expressive conduct. But the licensing of words is invariably dangerous, and the First Amendment therefore centrally and without qualification barred the licensing of words. Thus, although makes sense to say that freedom of speech is not absolute at the periphery of the freedom, it is profoundly misleading to say this about the core freedom from licensing. Indeed, the doctrines that suggested as much have cut a gaping hole in the center of the First Amendment, for they have left room for the government to justify itself in doing what the amendment most clearly forbade.

\textit{Consequences}.--This is not the place to examine in detail how the Court’s speech doctrines have legitimized the licensing of speech and the press. But it is revealing to examine the effects of at least one such doctrine—the overgeneralization that the freedom of speech is subject to compelling government interests and thus is not absolute.

After the Supreme Court repeatedly said that the freedom of speech was not absolute, and that speech rights were subject to compelling government interests, HHS and other government agencies felt fully justified in imposing the IRB licensing. For example, a consultant to the government defended the licensing by reciting that “the First Amendment is not an absolute bar to prior restraint.”\(^{26}\) Similarly, a key government commission reported that the government could regulate research methods “in order to protect interests in health, order and safety.”\(^{27}\)

The implications of such doctrines became painfully apparent when Ithiel de Sola Pool—a distinguished political theorist—protested against the licensing. During the drafting of the current regulations in 1980, he complained that, notwithstanding the recent experience with McCarthyism, IRB licensing would be “a more fundamental attack, because it would institutionalize a system of censorship over what is at the very

\(^{26}\) Robert Levine, Ethics and Regulation, 359 (citing Lawrence Tribe).

heart of free speech, namely, inquiry into political, economic, and social matters, which has always been precisely the thing that people could do at will, without asking anyone.”

The regulators, however, confronted Pool with the Supreme Court’s doctrine that the freedom of speech is not absolute. Pool therefore felt obliged to retreat to the “balancing” approach and pathetically had to concede, “we all understand that freedom of speech is not absolute.” The advocates of the licensing then triumphantly told him that the Court’s doctrine “require[d] an argument as to why the impermissible impact on speech is not justified by legitimate state interests.” Judicial doctrine seemed to justify the licensing, and for decades after Pool’s defeat, no academic (let alone any academic institution) questioned the constitutionality of the IRB laws.

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28Transcripts of Proceedings, President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 243 (July 12, 1980), Box 37, Special Collections, National Reference Center for Bioethics Literature, Georgetown University.

29Letter from Ithiel de Sola Pool to Morris Abrams & Alexander M. Capron (July 29, 1980), President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Box 3, Special Collections, National Reference Center for Bioethics Literature, Georgetown University.

30Letter from Alexander M. Capron to Ithiel de Sola Pool (Aug. 13, 1980), President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Box 3, Special Collections, National Reference Center for Bioethics Literature, Georgetown University.
The path toward licensing was paved with the best of intentions. HHS aimed to protect the public from harm, and the Supreme Court hoped to secure a broad freedom of speech. But the medical vision of harm included speech harms that are not legally cognizable, and the judicial doctrine defining the periphery of free speech was stated so broadly that it cut into the core freedom from licensing. Licensing thus became plausible.

VI. THE HARMS

A final question concerns not the law, but the underlying harms. Although the First Amendment flatly barred licensing, the harms from human-subjects research have seemed to legitimize the licensing, both legally and morally. This essay therefore must close by examining the harms. What are they?

Harms Caused by Human-Subjects Research. --In theory, the IRB laws are necessary to protect “human subjects” from harm arising in research. Certainly, what is done in the course of research can cause injury. But is it true that human-subjects research is distinctively harmful? And if not, how can the fear of harm justify the licensing?

When discussing the harms arising from human-subjects research, many apologists for IRBs cite the injuries arising in FDA drug trials. As already noted, however, the IRB laws--the laws that generally impose licensing on human-subjects research--are different from the FDA regulations, even though the latter also make use of IRBs. The harms resulting from FDA drug-trials thus occur under their own regulatory scheme; they do not result from the laws under consideration here.

Apologists also frequently cite the notorious mid-twentieth-century studies, such as the Tuskegee syphilis study, the Willowbrook hepatitis research, and the Army radiation experiments. These famous cases, however, do not show the danger of human-subjects research in general. Instead, they illustrate something more specific: the danger of government medical research.

These studies involved research by government medical personnel on patients who either were wards of government or were otherwise dependent on government. In such circumstances, medical personnel are not apt to feel constrained by the market or by negligence law. On the contrary, being government agents engaged in the pursuit of the public good, they tend to feel profoundly empowered. It therefore is unsurprising that government medical research (especially when done on wards of government or other dependent persons) has repeatedly led to abuses. But there is no reason to attribute the dangers of government medical research to other human-subjects research.

Indeed, there is no scientifically-serious empirical evidence that, overall, human-subjects research is particularly dangerous. Of course, some research projects
do cause injuries. Yet there is no scientifically-serious empirical evidence that, overall, anything is more harmful when done in research than when done in other circumstances. Nor is there any such evidence that, overall, anything done with intent to learn generalizable knowledge, or done with intent to publish, is more harmful than when done for other purposes. Nor is there any such evidence that any of these things are more dangerous when done by academics than when done by others.

In fact, the article most frequently cited to show the harmfulness of human-subjects research turns out to be unreliable. Thomas Beecher’s 1966 article in the *New England Journal of Medicine* famously describes 22 studies that involved unethical human-subjects research. But his article suppresses the identities of the researchers who conducted these studies, as well as the relevant citations, apparently because Beecher considered the researchers to be his human subjects.31

This suppression of evidence allowed Beecher to get away with sloppy research. The citations to the studies examined by Beecher have recently come to light, and the suppressed information reveals that Beecher represented his evidence in a self-serving manner. In fact, of the 22 studies, three were not American research projects and were thus irrelevant for understanding the dangers of American research. Of the remaining 19, at least 14 apparently included patients in government institutions. The 14 studies, moreover, were probably carried out by researchers with ties to the government. (Many of them probably were government employees or at least were funded by the government.) Thus, Beecher’s evidence does not show the danger of human-subjects research in general, but instead confirms the danger of mixing the government with medical research. In particular, it shows the danger of research done by government or government-funded medical personnel on persons within the control of government.32

Many commentators concede that IRBs should not be applied to the social sciences, but insist that IRBs are necessary for regulating biomedical research because that involves dangerous physical interactions. Once again, however, there is no evidence that physical interactions are more dangerous when done in academic or other publishable research, even in biomedical research, than when done in other circumstances, such as a doctor’s office, a football field, or a cosy bed. On the contrary, physical interactions probably are slightly safer in research than elsewhere.

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31Henry K. Beecher, “Ethics and Clinical Research,” 274 New Eng. J. Med. 1354 (1966). The role of Beecher’s study in justifying the licensing raises interesting questions about research ethics. Beecher suppressed the identities of his human subjects to protect them from embarrassment and other harm, but he thereby hid the real import of his data, prevented other scholars from testing his conclusions, and provided a false foundation for the imposition of licensing on non-governmental research. It therefore is necessary to reconsider what constitutes unethical research. Although medical ethicists tend to assume that ethical dangers come mainly from publishing information, there may be even more serious dangers from suppressing information, such as the self-suppression in Beecher’s case or the government suppression that was based on Beecher’s work. Indeed, when one considers how Beecher’s suppression of information justified the government’s suppression of research and its publication, his work appears to be among the most damaging in American medical history.

Even if physical interactions really were more injurious in academic research than in other circumstances, there would be many ways of regulating the harm without licensing speech. If the goal is generally to regulate injurious conduct, there already are applicable laws, such as negligence. If the goal is to regulate specific types of physical interactions, the government can easily adopt additional laws directed at these acts. The government therefore has no need to impose unconstitutional licensing of speech.

**Harms Caused by the Licensing of Speech.** -- If one is genuinely worried about harm, one needs to consider not only the harm from human-subjects research but also the harm from suppressing knowledge. This is what systematically hurts and even kills people.

IRBs annually censor thousands of research proposals. The exact number of proposals that come before IRBs under the IRB laws is difficult to discern, for IRB records are secret, and they do not typically differentiate the proposals that come under the human-subjects research regulations from those that arise under FDA regulations. Nonetheless, the proposals reviewed every year clearly run into the tens of thousands, and by some estimates well over 100,000. In addition, an uncertain but large number of projects are never begun or are abandoned because of the IRB laws, this being the “chilling effect.” One way or another, the IRB laws lead to widespread abandonment, alteration, and other suppression of research.

At least some of what get suppressed might otherwise have had profound effects in saving and improving lives. Imagine that each year a single transformative project gets suppressed on account of the censorship. Even if only one such project is lost, the consequences for human life are sobering. If one adds up the costs over decades, it is difficult to avoid the conclusion that IRBs cause far more harm than they ever could prevent. The cost of IRBs therefore must be measured in the lives of people across the globe who have been deprived of the benefits of research.

The lethal effects came to light in 2006 in Michigan. When catheters are introduced near the heart in intensive care units, they often cause fatal bloodstream infections. Some researchers from Johns Hopkins therefore attempted an experiment in Michigan hospitals to test whether the infections could be reduced by instituting simple check lists—requiring, for example, that the doctors wash their hands before inserting the catheter.  

The check list approach has since been made famous by Atul Gawande, and it was very successful. According to the New York Times: “Within three months, the rate of bloodstream infections from these I.V. lines fell by two-thirds. . . . Over 18 months, the program saved more than 1,500 lives and nearly $200 million.”  

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publishing the study were even greater, for every year, in the United States alone, there were perhaps 80,000 catheter-related bloodstream infections, resulting in up to 28,000 deaths, with annual costs of over $2 billion.\textsuperscript{35} The study thus clearly has saved many lives, not to mention the money.

But the key point here is the role of the IRB licensing. The researchers dutifully got IRB permission before they began their research, but after the study was well underway, HHS concluded that the IRB had not met HHS’s licensing standards. To be precise, the IRB should have required the researchers to treat not only the patients but also the doctors as their human subjects. Under the logic of the IRB laws, HHS was right, but under such a requirement, the researchers probably would not have been able to do their study. On account of the IRB’s failure to comply with HHS’s standards for licensing, HHS ordered the Johns Hopkins doctors to shut down the ongoing research. Fortunately, however, HHS acted too late to stop the research altogether or to prevent its publication.

The Michigan case therefore is revealing. By escaping the licensing, it shows how much might have been lost if the IRB had done its job under the IRB laws. The suppression in this one case alone would have cost more than ten thousand lives every year.

Nonetheless, it is difficult to do a body count. Although the Michigan case reveals the scale of the losses that can occur in even a single case, how can one measure the full range lives not saved or improved as a result of the suppression? Because the suppressed research was not completed, or was completed only in censored form, one cannot what determine what benefits might have ensued. The overall losses to life and limb, however, are extensive. They evidently extend to thousands, even tens of thousands or more, each year. Put graphically, the annual losses greatly exceed the combined costs imposed by many mass murderers. Of course, IRBs do not physically stab individuals, but they strangulate the inquiry and publication that would have kept untold thousands alive.

The harm done by the licensing obviously is especially extensive in biomedical research. As already noted, apologists for IRBs often take the fallback position that, even if IRBs are unnecessary in the social sciences, they are essential for the biomedical sciences. This is puzzling, however, for medicine is precisely where IRBs have the highest death toll. The suppression of words is harmful in all areas of inquiry—for example, in both political science and pathology—but the harms are most clear where the interference with inquiry and publication leaves numerous patients to die.

In fact, the harm caused by the licensing of biomedical research is much greater than the harm it prevents. Most biomedical research on human subjects examines only a limited number of persons in order to explore theories designed to help much larger

numbers in the general public. Thus, almost inevitably, the harms prevented by IRBs are relatively small compared to the harms they cause. In addition, biomedical research tends to become the foundation for yet more such research, which then benefits even larger numbers. Consequently, whereas the harms prevented by IRBs expand only arithmetically, the harms caused by them tend to expand exponentially.

In a society based on freedom of inquiry and publication, the IRB licensing is literally deadening. It has reduced many scholars to misery. It has ruined much scholarship. It has impeded graduate education. It has stifled whole areas of learning. And it has obstructed the advancement of knowledge, with increasingly lethal results.

**Political Harms.** --Of course, the licensing is harmful in ways that go beyond the deaths and other immediate costs, for the licensing has political consequences. It already has been noted that licensing inverts the relationship of individuals to government. At a more practical level, how can the people have well-informed opinions about their government’s policies, if the government censors almost all direct study of persons affected by its policies?

Consider, for example, the healthcare regulations issued by HHS. This executive department exercises the full range of government powers: It legislates regulations; it enforces them; it adjudicates disputes under them. Because HHS and other government departments exercise so much power with so little formal accountability, the freedom of speech has become ever more important—far more so than when laws were made merely by Congress. The freedom of speech, however, is now subject to licensing under HHS regulations.

In fact, by means of the IRB laws, HHS stifles a sort of inquiry that once was a major source of information about healthcare and its delivery. Academic studies of human subjects traditionally were uncensored, and through their radical critique of government, they did much to shape the establishment of government health services. Now, however, the very government department that imposes healthcare regulations also imposes licensing on much of the academic study of healthcare. It thereby profoundly limits the studies that draw information at a personal level from doctors, nurses, administrators, patients, and their families. Such studies are essential for judging any healthcare policy, but they have been largely stultified, for they cannot be begun, let alone published, without IRB permission.

HHS is confident that its data allows it to make good judgments about how to regulate healthcare. But HHS licenses and thereby discourages, alters, or otherwise suppresses much of the independent academic research that directly studies human beings and their experiences with healthcare. The result is calamity for both HHS and the public. HHS regulates the public, and is judged by the public, on a scientific record that HHS has largely crushed under its censorship.

The licensing even bars academics and students from interviewing most persons in government, let alone publishing the interviews, without first getting IRB permission.
To be sure, there is a “public official” exemption, but the government interprets it very narrowly to include, at most, only heads of agencies.\textsuperscript{36} As a result, almost all public officials or employees (including those from whom one might learn what actually is happening in agencies) are protected from inquiry. And even officials in exempted research are protected, for although such research is exempt from the Common Rule, it remains subject to review to ensure its compliance with the ethical principles of the Belmont Report and any additional local rules.\textsuperscript{23} As explained by the National Science Foundation, even “[w]hen the subjects are public officials or candidates for public office,” IRBs should ensure “respect for respondents to guard their privacy.”\textsuperscript{24}

To understand the political implications, consider that all HHS officials are thus protected by the licensing. So too are all members of IRBs. An academic or student therefore cannot interview such officials or members for academic purposes without first submitting to the censorship, which is designed to protect the interviewees from embarrassment and other ordinary consequences of speech. As a result, empirical academic critiques of HHS decisionmaking, and even of IRB licensing, are profoundly difficult—often practically impossible.

\textsuperscript{36} The Common Rule exempts research “involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section,” if “the human subjects are elected or appointed public officials or candidates for public office.” 45 C.F.R. § 46.101(b)(3). Nonetheless, there is good reason to believe that OHRP has interpreted “public officials” to mean only public figures, and even reforms proposed by SACHRP seem to take only a slightly softer version of this, apparently distinguishing between heads of agencies and less officials. According to SACHRP, OHRP’s “guidance should include examples of ‘public officials.’ In particular, the guidance should include examples that OHRP has provided in the past, such as university faculty, public school teachers, and police officers in general are not considered to be elected or appointed public officials, whereas mayors, governors, school superintendents, school board members, and police chiefs are considered to be elected or appointed public officials.” SACHRP Letter to HHS Secretary (Sept. 18, 2008), Office for Human Research Protections (OHRP), Secretary’s Advisory Committee on Human Research Protections (SACHRP), at http://www.hhs.gov/ohrp/sachrp/sachrpletter091808.html. In fact, some IRBs have not exempted the study of even major figures, such as Ronald Reagan or federal judges.

\textsuperscript{23} 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.” OHRP, Guidance on Written IRB Procedures, §D(1), at http://www.hhs.gov/ohrp/policy/irbgd107.html. For practical purposes, this means a determination by the IRB. The exemptions in the Common Rule apply only to its policies, and thus, as the government makes clear in its Federal Wide Assurance, “All of the Institution’s human subjects research activities, regardless of whether the research is subject to the . . . Common Rule . . ., will be guided by a statement of principles,” almost always the Belmont Report. Terms of the Federalwide Assurance for the Protection of Human Subjects, §1, at http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html.

\textsuperscript{24} The NSF states: “When the subjects are public officials or candidates for public office, the research is exempt even when identifiers are included or disclosure might be harmful. However, all research should be bound by professional ethics and respect for respondents to guard their privacy whether or not the research is exempt (unless the participants understand that their information may be made public and permission is granted).” National Science Foundation, Division of Institution and Award Support, Frequently Asked Questions and Vignettes, at http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp. This sometimes is repeated in turn by universities and their IRBs. See, for example, University of Vermont, Committees on Human Research, Behavioral Module, at http://www.uvm.edu/irb/education/supplemental/behavioral/section4-02.htm; Classroom Research Conducted by Students, 9, at George Mason University, College of Education and Human Development, at cehd.gmu.edu/assets.
In these circumstances, what does it mean to say that Americans live in a free society? The government aims to act responsibly on the best information it can get, and the people try to evaluate their government on the basis of the information available to them. But the government systematically suppresses the very sort of academic inquiry and publication that could illuminate central political questions and that could shed light on the persons who exercise power.

Even Deeper Harms. --Alarming as the political costs are, the harms go even further, for they threaten the very nature and success of modern society. Francis Bacon long ago envisioned the progressive amelioration of the human condition, and indeed modern life has come to center on human beings and their material comforts. This vision of life, however, rests on empirical experimentation about human beings, and therefore when licensing threatens such experimentation, it imperils the nature and prosperity of modern society.

Intellectual inquiry always will cause discomfort among dominant forces in a society, whether egalitarian or hierarchical. Socrates studied human nature in a way that seemed to challenge the deities of the city, and for this the demos condemned him to death. Galileo studied the nature of the universe in a way that seemed to offend the dignity of God, and for this the hierarchy imprisoned him. In our society, the dignity of God is left by the wayside. But the dignity of human beings has been elevated, and to offend this is to incur the wrath of the demos—at least, that is, the populist wrath of those who claim to speak for the people.

In other words, academic inquiry continues to inspire anxiety, and this anxiety continues to prompt the desire to suppress. What has changed is merely the object of concern. Whereas anxiety about God’s dignity inspired the Inquisition to suppress the study of the heavens, anxiety about human dignity inspires HHS to suppress the study of human beings.

Life itself is a sort of experiment, in which we learn from experience, and modern society is a sort of experiment in living. Such a society depends for its prosperity and very nature on empirical studies of human beings, perhaps especially inquiries that test and challenge our most basic assumptions. This can be unnerving, but what is even more worrisome is that the government of the United States now responds with licensing of speech and the press.

CONCLUSION

Although much has changed since the seventeenth century, much is the same. In the seventeenth century, the Inquisition and the Star Chamber licensed the press. Now IRBs license both speech and the press. Licensing is back, this time even more intrusively than in the past.
Fortunately, no amount of censorship can obscure the truth about the censorship. The licensing imposed under the IRB laws is utterly unconstitutional. If a Newspaper Review Board for journalists would be unconstitutional, so is an Institutional Review Board for faculty and students. In fact, it difficult to find a more systematic and widespread violation of the freedom of speech and the press in American history.

The First Amendment recognizes that America is an experiment in freedom and that this depends on the freedom of speech and the press. The amendment therefore establishes this freedom as a constitutional right, and on this foundation Americans can resist the current licensing. Socrates died for his freedom. Galileo went to prison for his freedom. All that Americans need is a judge who is willing to enforce the Constitution.