

## “INGENIOUS ARGUMENTS” OR A SERIOUS CONSTITUTIONAL PROBLEM? A COMMENT ON PROFESSOR EPSTEIN’S PAPER

*Philip Hamburger\**

In his observations about IRBs, Professor Richard Epstein makes persuasive arguments about the dangerous reach of the IRB laws, but he prefaces this policy analysis with a brief excursus into constitutional law that requires some comment. His view is that the constitutional debate over IRBs arises not so much from a substantial constitutional problem as from “ingenious arguments.”<sup>1</sup> Yet this conclusion rests on mistaken assumptions—both about the IRB laws and about the constitutional objections—and because so much is at stake in the constitutional question, it is necessary to point out the inaccuracies.

The first set of mistaken assumptions relates to the IRB laws.<sup>2</sup> Professor Epstein doubts there is any serious constitutional problem with the IRB laws, and certainly if they are understood in accord with popular assumptions about them, the constitutional issues are not as sharp as some of us have suggested. The laws, however, repay careful study.

On the question of the obligation of law, for example, it is taken for granted by Professor Epstein that the force of the IRB laws rests entirely on conditions that the federal government places on its research grants.<sup>3</sup> In fact, the government ensures compliance with the Common Rule by relying not only on these conditions but also on state negligence law.<sup>4</sup> The federal government no longer overtly pressures universities, as a condition of federal funding, to apply IRBs to research that lacks federal funding, but the

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\* Maurice and Hilda Friedman Professor of Law, Columbia Law School.

<sup>1</sup> Richard A. Epstein, *Defanging IRBs: Replacing Coercion with Information*, 101 NW. U. L. REV. 735, 736 (2007) (link).

<sup>2</sup> By which is meant the Common Rule and the associated regulations and laws, federal and state—not the FDA laws and regulations. See Philip Hamburger, *Getting Permission*, 101 NW. U. L. REV. 405, 406, 421 (2007) (link).

<sup>3</sup> Epstein, *supra* note 1, at 737.

<sup>4</sup> The Common Rule is the federal regulation that sets the basic federal standards for the licensing of human subjects research by IRBs. 45 C.F.R. § 46 (2005). For the pressures felt by universities under state negligence law, see *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME: BULL. OF THE AM. ASS’N OF U. PROFESSORS, Sept.–Oct. 2006, at 55, 60 (link). See also Hamburger, *supra* note 2, at 445–48.

government was able to abandon this requirement precisely because it had earlier used its conditions on research to elevate IRB licensing as the standard of care for research. It could therefore rely on state negligence law to induce universities to apply IRBs to all human subjects research, regardless of the source of funding.<sup>5</sup> As a result, although the conditions requiring the use of IRBs remain significant, and although they are probably unconstitutional, the most far reaching constraint comes in the form of state negligence law. This is clearly a matter of state action and, if only on this account, one cannot easily conclude that the IRB laws lack sufficient obligation of law to pose a constitutional problem.

Professor Epstein is also mistaken about the IRB laws when he assumes that they concern conduct rather than speech or the press. This is certainly the popular view of the matter, and it is true that the government carefully drafted its regulations to apply to “research.”<sup>6</sup> Yet the regulations define research as a “systematic investigation” designed to produce “generalizable knowledge,” which was intended to mean attempts to produce scientific hypotheses.<sup>7</sup> In requiring universities to impose IRBs, the government even asks the universities to acknowledge that “generalizable knowledge” is that which is “expressed . . . in theories, principles, and statements of relationships.”<sup>8</sup> As if this were not bad enough, it is widely recognized (not least by IRBs and government committees) that a “systematic investigation” designed to develop “generalizable knowledge” necessarily means what a researcher “plans to publish” or what is “publishable”—this being part of the government’s scientific conception of research.<sup>9</sup> Taken together, these details would seem to suggest that the IRB laws focus on speech and the press. Of course, there is always room for a contrary perspective, and Supreme Court doctrine only confuses the matter, as I have argued at length. But when the government insists that it is regulating that which is “expressed . . . in theories, principles, and statements of relationships,” it is not unreasonable to take the government at its word.

A final mistake about the IRB laws made by Professor Epstein is his assumption that the concerns about speech are merely incidental—that “the speech interests implicated in university research (especially in the biomedical area) are often tangential” or “‘incidental’” to the “major, or at least ostensible, purpose” of the regulations, which is protecting “health and safety.”<sup>10</sup> This observation is problematic because it does not adequately

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<sup>5</sup> See Hamburger, *supra* note 2, at 445–48.

<sup>6</sup> *Id.* at 430.

<sup>7</sup> 45 C.F.R. § 46.102(d) (2005); see also Hamburger, *supra* note 2, at 430–31.

<sup>8</sup> NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 44 Fed. Reg. 23,192, 23,193 (Apr. 18, 1979); see also Hamburger, *supra* note 2, at 431.

<sup>9</sup> Hamburger, *supra* note 2, at 431–32.

<sup>10</sup> Epstein, *supra* note 1, at 736.

acknowledge the application of the regulations to behavioral research, including purely verbal inquiry in the social sciences, the humanities, and various professional fields (including law and journalism).<sup>11</sup> More centrally, Professor Epstein’s assumption about the incidental character of the speech interests mistakes what IRBs typically do under the regulations: IRBs protect health and safety mostly by suppressing what is said and printed. Whether acting directly or through various indirect mechanisms, IRBs deny permission until academics submit to modification and other censorship of their publications, their questionnaires, and even their conversations.<sup>12</sup> This censorship is the most common activity of IRBs—probably at a rate of at least 100,000 times a year and, by some estimates, many times that rate—and it is therefore difficult to conclude that the censorship is “incidental.”<sup>13</sup> Professor Epstein’s conclusion that the speech interests are incidental to the goal of “health and safety” is perhaps most troubling because it ignores the government’s astonishingly broad conception of health and safety. The regulations were carefully written to treat disturbing ideas and unsettling questions as a health risk, and when the law deliberately categorizes provocative ideas and inquiries as a “health and safety” problem, the concerns about speech cannot be considered merely “incidental” to the question of “health and safety.”<sup>14</sup>

These points about the IRB laws—that they rely on the direct force of law as well as conditions, that they focus on speech and the press, and that the First Amendment implications are not incidental—should already be enough to suggest the seriousness of the constitutional problem. Of course, this is not to say that the IRB laws are necessarily unconstitutional. Perhaps, notwithstanding the Supreme Court’s recent language, the government can evade the First Amendment by using conditions to regulate and even license speech and the press.<sup>15</sup> Perhaps the states can use the direct

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<sup>11</sup> For the way IRBs have silenced students and academics in journalism schools, see Hamburger, *supra* note 2, at 471.

<sup>12</sup> IRBs will protest that they usually do nothing more intrusive than adjust informed consent documents, but that is precisely the point, for control over informed consent is one of the key mechanisms by which IRBs impose censorship. IRBs often spell out their restrictions in the informed consent documents that IRBs require researchers to give to human subjects. Accordingly, a process that sounds as innocent as the informed consent obtained by a doctor from his patient turns out, in fact, to be a mechanism for suppression of speech and the press. *Id.* at 433. For the sharp differences between medical informed consent and the informed consent required by IRBs, see *id.* at 438–39.

<sup>13</sup> See *id.* at 407, 469, 484; conversations with IRB members.

<sup>14</sup> For the treatment of “sensitive” questions under the IRB laws, see *id.* at 439, 460–63.

<sup>15</sup> For suggestive language about the constitutional limits regarding the government’s use of conditions on speech in academic institutions, see *Rust v. Sullivan*, 500 U.S. 173, 200 (1991) (link) (“[T]he university is a traditional sphere of free expression so fundamental to the functioning of our society that the Government’s ability to control speech within that sphere . . . is restricted by the vagueness and overbreadth doctrines of the First Amendment.”). See also *Rumsfeld v. F.A.I.R.*, 547 U.S. 47, 60 (2006) (link) (“Because the First Amendment would not prevent Congress from directly imposing the Solomon Amendment’s access requirement, the statute does not place an unconstitutional condition on the receipt of federal funds.”); Hamburger, *supra* note 2, at 445, 451.

force of law to impose licensing of speech and the press as long as the licensed activity is defined so broadly that it also includes “conduct.” Perhaps the consequences for speech remain merely incidental when disturbing speech is defined as a threat to “health and safety.” Perhaps. But whatever one thinks about such possibilities, the constitutional problem is sobering.

The second set of mistaken assumptions involves Professor Epstein’s understanding of the constitutional objections. Most generally, he assumes that my analysis of the IRB laws is a claim about the surface of Supreme Court doctrine and the likely outcome of any litigation.<sup>16</sup> My argument, however, has always been that Supreme Court doctrine has given the appearance of constitutional legitimacy to the IRB laws and that these laws thereby reveal why such doctrine needs to be reconsidered.<sup>17</sup>

More concretely, Professor Epstein is under the impression that “the major constitutional attack” on the IRB laws “treats them as a garden-variety form of prior restraint.”<sup>18</sup> Such an argument would, indeed, be an uphill struggle. My argument, however, specifically rejects analysis in terms of prior restraint and instead focuses on the question of licensing.<sup>19</sup> Although the surface of Supreme Court doctrine on prior restraint does not distinguish between licensing laws and judicial injunctions, the cases treat the former more severely, and with good reason, for licensing is widely recognized as more dangerous than injunctions.<sup>20</sup> It is open to debate whether my argument about licensing is correct, but given that my articles on the subject focus on the distinctive character of licensing and how licensing differs from the more general question of prior restraint, it is puzzling why anyone would suggest that my argument treats the IRB laws “as a garden-variety form of prior restraint.” This is exactly what my work does not do.

Professor Epstein further mistakes the constitutional objections when he discusses the distinction between facial and applied challenges.<sup>21</sup> It is true that my argument distinguishes between First Amendment tests based on the words of the regulations and those based the words of the persons regulated.<sup>22</sup> It does not address, however, the question of facial and applied challenges or any other question about the posture of litigation.

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<sup>16</sup> See Epstein, *supra* note 1, at 736–37.

<sup>17</sup> See Hamburger, *supra* note 2, at 407, 410, 440, 452, 491–92. In fact, the debilitating effect of Supreme Court doctrine is the primary theme of Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV., 271, 277–81, 353–54.

<sup>18</sup> Epstein, *supra* note 1, at 736.

<sup>19</sup> The very title of *Getting Permission* indicates its main theoretical point: that licensing differs from other prior restraint because it requires one to get permission. Hamburger, *supra* note 2, at 405 *passim*.

<sup>20</sup> *Id.* at 415.

<sup>21</sup> Epstein, *supra* note 1, at 736.

<sup>22</sup> Hamburger, *supra* note 2, at 429, 437.

In sum, although Professor Epstein’s paper is illuminating on the policy question, it is disappointing on the constitutional problem because it rests on mistaken assumptions. Many commentators have been misled by popular assumptions about IRBs, but this is all the more reason to dig deeper into the regulations and the constitutional law and thereby to confront the grim reality.

The danger is nothing less than licensing of academic attempts to form scientific hypotheses. It is an assault on freedom that rises far above ordinary government intrusions and harks back to the fate of Galileo.<sup>23</sup> The particular constitutional threat is the licensing of speech and the press—an utterly repressive mode of control, which was abandoned in the seventeenth century, prohibited in the eighteenth, and surreptitiously revived in the twentieth. More generally, the constitutional threat arises from the Supreme Court’s own First Amendment doctrine. In developing its doctrine on speech and the press, the Court ended up giving the appearance of legitimacy to the very laws—licensing laws—that the Constitution’s speech and press guarantees were most clearly designed to forbid.<sup>24</sup> This legitimization of licensing is disturbing, and how it happened, and how it has been used against academics, is something that an academic might well take seriously.

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<sup>23</sup> See *id.* at 47–83.

<sup>24</sup> See *id.* at 407, 410, 440, 452, 491–92; Hamburger, *The New Censorship*, *supra* note 17, at 277–81, 353–54.