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Defanging IRBs: Replacing Coercion with Information

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INTRODUCTION

The articles in this Symposium contain many well-directed criticisms of the dominant practices of Institutional Review Boards ("IRBs") in both the biological and the social sciences. The trenchant criticisms against the IRB procedures and protocols fall into two broad groups: those which are directed to the wisdom of the various practices, and those which are directed to the alleged constitutional infirmities of the current IRB procedures. The substantive critique stresses the general dangers of IRB oversight.[1] In biomedical cases, the delays are extensive, and the need for documentation is exhaustive, so that the opportunities for progress labor under an ever heavier form of government and institutional oversight—where the latter is often used in order to provide the universities a shield against powerful government sanctions. In the behavioral sciences, these concerns remain, but they are compounded by an aggressive unwillingness to allow social science research to probe such controversial topics as date rape, academic cheating, and nude dancing, for fear that a discussion of those topics might do harm to the human subjects who participate in the research project.[2] Right now, it appears necessary to receive IRB clearance to conduct the interviews needed for oral history projects.[3] The First Amendment may praise a culture in which debate is "uninhibited, robust, and wide-open," even if that debate "may well include vehement, caustic, and sometimes unpleasantly sharp attacks on government and public officials."[4] But the IRB culture often waters down any questions asked of public figures (or ordinary persons, for that matter) for fear of upsetting people whose

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[1] *See* Dale Carpenter, *IRBs, Regulatory Incentives, and Some Modest Proposals for Reform*, 101 NW. U. L. REV. 687 (2007); Robert Charrow, *Protection of Human Subjects—Is Expansive Regulation Counterproductive?*, 101 NW. U. L. REV. 707 (2007).

[2] *See, e.g.*, Carpenter, *supra* note 1, at 691–94. For a number of sensible, if modest, proposals for reform, see *id.* at 699–704.

[3] *Id.* at 691.

[4] *See* New York Times Co. v. Sullivan, 376 U.S. 254, 270 (1964).

lives were steeped in controversy. The individuals who may be freely abused in public life are entitled to a sheltered life thereafter, at least from the prying eyes of academic researchers.

The major constitutional attack on government IRBs treats them as a garden-variety form of prior restraint in violation of the First Amendment,[5] a view which has been voiced most forcefully by Philip Hamburger.[6] As a matter of current law, the First Amendment does not appear to place any strong restraints on the activities of IRBs in their dealings with either government-funded or private research undertaken in universities. In Hamburger's view, which he reiterates in this volume, the entire system represents an obnoxious form of prior restraint through a licensing system that requires all investigators to come hat-in-hand to review boards whose every procedure bears the heavy sign of government interference. On this issue, I wish that I could agree with his facial constitutional condemnation, but regrettably, I do not.[7] I do not think that his ingenious arguments overcome the objection that the speech interests implicated in university research (especially in the biomedical area) are often tangential (or, as constitutional lawyers are fond of saying, "incidental") to their major, or at least ostensible, purpose of protecting the health and safety of the ordinary people who are recruited into these various research endeavors. Facial challenges are therefore likely to fail, even if some applied challenges may succeed.

The constitutional case against the frontal assault on IRBs, moreover, is strengthened, if not clinched, because the government ties its vast regulatory apparatus to the receipt of its own research dollars, so that it becomes research institutions to take the bitter with the sweet. If they wish to be part of the government program, then they must play by the rules that government, like any other grantor, sets. The application of these rules for government-funded research are hard to displace categorically on any of the traditional tests for unconstitutional conditions.[8] These conditions are surely germane to the grant. Nor do they involve the obvious exercise of state monopoly power given that other sources of funds are available. Given their usual imperial instincts, government officials may insist that all other projects funded by private universities be subject to similar oversight

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[5] *See* Renée Lettow Lerner, *Unconstitutional Conditions, Germaneness, and Institutional Review Boards*, 101 NW. U. L. REV. 775 (2007); James Weinstein, *Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493 (2007).

[6] *See* Philip Hamburger, *Getting Permission*, 101 NW. U. L. REV. 405 (2007) [hereinafter Hamburger, *Getting Permission*]; *see also* Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271 [hereinafter Hamburger, *The New Censorship*].

[7] For an exhaustive defense of the constitutionality of these boards, see Weinstein, *supra* note 5. For his rejoinder, see Hamburger, *Getting Permission*, *supra* note 6.

[8] *See* Weinstein, *supra* note 5, at 552–57. For my general views, see RICHARD A. EPSTEIN, BARGAINING WITH THE STATE (1993); Richard A. Epstein, *Unconstitutional Conditions, State Power, and the Limits of Consent*, 102 HARV. L. REV. 4 (1988).

even if they do not involve the expenditure of public funds. But here universities are single entities, and, after the Supreme Court upheld the Solomon Amendment,[9] it is a losing fight to claim that government conditions are solely applicable to the organization unit that receives the grant. The debate on this issue will go forward, but its outcome is largely preordained. The current culture of constitutional deference makes it unwise for any lawyer to mount a frontal assault on IRBs on a contingent fee basis. Indeed, in a sense the situation is worse. Let any institution win an unconstitutional conditions challenge, and all future grants will just dry up. The better way to do research is through independent organizations that receive no government funding—unless the government contrives ways to extend its regulatory net, which I suspect and fear it will.

Rather than struggle mightily against the odds, I prefer to offer a different perspective to this problem that pays little or no attention to the present structure of constitutional law. Accordingly, my mission is to raise this question of first principle. If we had a sensible small government state, what would be the proper way to fund and control various forms of research both in biology and in the social sciences? I make no pretense that the answers to this question will resonate with either current law or practices. And I undertake this inquiry in order to lay bare what are, I think, the major sources of uneasiness with the entire IRB enterprise, as it has lurched out of control. In order to do this we shall take nothing for granted at the outset, including the power of the federal government or the states to regulate various kinds of research. Some people will reject my recommendations for reform, but I hope that they will nonetheless join the ranks of the many who think that the present political equilibrium has shifted too far in the direction of massive federal regulation.

Accordingly, Part I briefly explains why the control of force and fraud is a legitimate government function. Part II then looks at the remedial structure, both public and private, that should be used to deal with the control of fraud and misinformation, which lies at the core of the IRB mission. Part III then examines how the *Belmont Report*, which contains the canonical justifications for IRBs, makes a series of key conceptual errors that expand the government's role in providing information for private choices into an arrogation of power that removes the possibility of private choice. Part IV then proposes a brief alternative system that seeks to remove from the IRB the power to block any biomedical or behavioral research, but allows it the right to comment publicly on any and all proposals for research that it can review before individual people choose to sign up. The government should have the right to post messages on a public bulletin board, not to shut down all programs that do not meet its most exacting standards.

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[9] *See* Rumsfeld v. Forum for Academic and Institutional Rights, Inc., 126 S. Ct. 1297, 1306–07 (2006).

I. THE CONTROL OF FORCE AND FRAUD: CHOOSING THE RIGHT REMEDIAL MIX

At one level, the case for IRBs has often been defended by an appeal to narrow libertarian principles that grant the state the power to control the use of force and fraud by private parties. The appeal for this government function rests on the simple view that unconstrained use of either technique leads to unacceptable social outcomes that cannot be cured by voluntary actions alone. Hence the standard social contract theory allows the state to demand each individual renounce the use of these techniques in dealing with others. Thereafter it must supply remedies, either public or private, against these various forms of misconduct.

In the context of medical research, force is of little concern, but fraud surely is a more serious matter that has special urgency, especially on biomedical matters. First, the information relevant to medical treatment in general and scientific research more generally is sometimes present but hard to understand. Second, the competence of the individuals who are about to undergo medical treatment or to participate in research projects cannot be taken for granted. Medicine poses far greater risks than ordinary commercial transactions, where the first line of defense is always to stay out of markets that you do not understand (which is why I do not, for example, trade options). Yet people with serious chronic or acute conditions do not have that choice. They must participate in the market to survive. Yet the very conditions that drive them into the market can in many, but by no means all, cases compromise their competence to make what may prove to be the most important decisions of their lives. So these risks here are real, even for defenders of the minimal state.

The hard question is what remedy should be applied in these cases, and on that attitude the small government approach that I have long championed has a good deal to say about licenses and permits in general, most of which applies in this particular context. The remedial inquiry presents two different choices. The first of these asks the question of whether the remedy should come ex post or ex ante. The second question is whether the enforcement mechanism should be public or private. In both cases, the simplest solutions to this problem treat it as an all-or-nothing choice. But in reality, it is always possible to mix and match remedial strategies that, first, combine ex ante with ex post remedies and, second, rely on both public action and private relief. Ex post remedies include private actions for damages and fines and imprisonment by the state. Ex ante remedies include both injunctions and licenses.

The clear small government bias is twofold. The first is to rely on private remedies. The argument is that decentralized remedial action tends to obviate the risk of massive overkill that comes with government suits. The second is to rely on remedies ex post as opposed to remedies ex ante. The argument here is that the use of any form of ex ante remedy necessarily in-

fringes on an individual's freedom of action. That interference will prove very costly in those cases where the action that is prohibited did not result in any form of actionable harm that would justify the invocation of a remedy ex post. In addition, the availability of the ex post remedy should reduce the frequency of right violations that need remediation. The usual common law accommodation therefore tends to allow injunctions only in those cases where there has already been an occurrence of a particular type of harm that is likely to repeat, or the presence of some imminent threat of harm, such as death or serious injury, for which damages after the fact provide an insufficient remedy, which proves of great importance in cases where individual actors may be insolvent or beyond the range of legal process.

II. THE APPLICATION OF THE BASIC FRAMEWORK TO IRBS

This framework then carries over to dealing with the use of public force. In most cases the use of fines after the fact is unimportant because of the existence of private remedies. Nonetheless, in some cases, fines have an important role to play to deter conduct that is likely to cause harm if it goes unchecked. Speeding tickets are an obvious example. Likewise, the use of state licensing or injunctive power often makes sense where the likelihood of serious harm to someone is high, but the identity of the person harmed is not clear. Insisting on driving licenses to enter the public highways is an effective way to insure minimum competence on the highway. Suspending the licenses of people with accident records or multiple traffic violations is a substitute for the private injunction that no individual driver can be expected to bring. The pattern that emerges is to combine private rights of action after the fact with public intervention before the fact, except in those cases like nuisance disputes between neighbors where a single person or small group stands in the path of danger and thus has sufficient incentive to seek injunctive relief.

The question is how well this remedial framework applies to various kinds of injury that arise out of research settings. On the biomedical side, the risk of danger cannot be blithely ignored, as physicians and other health care professionals may have a tendency to lie to induce people to take treatment they do not need or to participate in research studies in which it is not in their best interest to participate. But this action is difficult to win. The standard elements in the action for fraud require the plaintiff to prove that the defendant made a false statement of fact with knowledge of its falsity or with reckless disregard for its truth. That statement must be material, so that it speaks to an issue of sufficient importance to sway the decision of a reasonable person. In addition, the plaintiff must rely on that statement to his or her detriment.[10]

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[10] *See* RESTATEMENT (SECOND) OF TORTS: LIABILITY FOR FRAUDULENT MISREPRESENTATION § 525 (1977).

This cause of action is hard to prove on all its elements, especially in medical settings, where people are awash in information of uncertain value whose impact it is difficult to trace. It is so hard to figure out what people would have done in the absence of the fraud, when still subject to serious gaps in information. Nor is it easy to disprove the contention that various patients would have died or been injured from natural conditions no matter what they were told. There is no need to belabor the full line of defenses open to defendants. It should suffice to say that even with the boom in medical malpractice cases, straight fraud claims are a rarity.

In order to overcome these obstacles, starting in the late 1950s, judges developed a doctrine of informed consent that placed physicians under a common law duty to supply a patient with information about the nature and extent of the risks in question.[11] At this point the law creeps beyond the libertarian prohibition against fraud by insisting that the physician needs to enhance patient autonomy by giving them the tools to make their own choices in a responsible fashion. As stated, informed consent has a built-in tilt that shapes the activities of modern IRBs. No physician had a comparable obligation to inform the patient of the *expected benefits* of the treatment. The asymmetrical disclosures were commonly justified as an antidote to self-interest against the physician hyping his or her own services.

The advent of this duty to disclose, however, did little to close the information gap. The law may require disclosure but it cannot ordain that the patient understand the import of what was disclosed. Even patients who ask about risks sensibly choose to rely on the advice of a physician whom they trust. Nor do these lawsuits hold much chance of success. Introduce disclosure requirements, and it is necessary to decide what should be disclosed. The harried plaintiff has to find the middle range in a familiar trichotomy. Obvious risks need not be disclosed because they are already known. Remote risks need not be disclosed because they should not bear on reasonable choices. Only mid-level disclosures (e.g., a 1% chance of paralysis or sterility) count, and usually these are not large enough to influence the choices of a patient in desperate straits. Nor if they are is it likely that the change in patient behavior can be tied to the adverse event.

The ideal of full information should not, however, be regarded as futile, as most people think that better information helps make better decisions, no matter what legal regime is in place. So the question is how to fill the gap. In my view, there is little room for injunctive relief under the imminent harm standard as there is little risk of rampant nondisclosures that have an adverse effect on patient behavior. Nor should that omission from the legal arsenal be the source of any great concern. In many situations, the supply and demand for information does not depend on the creation of

[11] For one powerful statement of the position, see Canterbury v. Spence, 464 F.2d 772, 780–83 (D.C. Cir. 1972). It is worth noting that the plaintiff lost at trial, and got no relief on appeal. *See* Canterbury v. Spence, 509 F.2d 537 (D.C. Cir. 1975) (unpublished table decision).

some legal duty to disclose. If that information counts, then hospitals and physicians will offer it even if patients do not ask for it. And patients will ask for it even if they are not required to do so. In the long run, therefore, the determinants of how much information will be supplied will depend on part of the cost of its production and the demand for its receipt.

On these two issues, moreover, the verdict of the last thirty years is unequivocal. As the options for good treatment increase, so too does the demand for information. As the cost of supplying information drops, the quantity supplied will be increased. Most significantly, the source of information need no longer be a treating physician. Hospitals can generate standard booklets that describe various procedures, and individuals can find lots of information from third party sources (whose bias may well be less) by use of a search engine. I just typed "hip replacement surgery" into Google and came up with over 4 million responses, the first of which was a veritable cornucopia of information.[12] That site was prepared by DePuy Orthopaedics, which sells replacement hip products, but all the links from it were not. And in any event, once this information becomes salient to individuals, neutral sites will spring up as well, given the lost cost of entry into this market. The independent sources of information should count as a powerful check against the dangers of self-interest. The problem of information remains hard at the level of individual choice, but there does not seem to be any systematic shortfall in its provision, especially today. Under the basic theories outlined above, therefore, we have no need for any form of private injunctive relief or public licensing. The history of IRBs reveals a very different attitude toward the basic problems.

III. THE BEECHER ARTICLE AND THE *BELMONT REPORT*

Without question, the most influential sources for the development of the IRBs are the famous 1966 Beecher article on clinical research[13] and the 1979 *Belmont Report*, based largely on deliberations held three years before.[14] That report was prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was created pursuant to the National Research Act of 1974, which led to the initiation of the current IRB procedures.[15] In dealing with the creation of IRBs, the background conditions were somewhat different from what they

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[12] DePuy Orthopaedics, Inc., HipReplacement.com: Restoring the Joy of Motion, http://www.hipreplacement.com/hip-home.html (last visited Nov. 12, 2006).

[13] Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966).

[14] NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIOR RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1978), *available at* http://ohsr.od.nih.gov/guidelines/belmont.html [hereinafter BELMONT REPORT]. The title comes from the name of the conference center at which the relevant deliberations were held.

[15] National Research Act, Pub. L. No. 93-348, 88 Stat. 1974.

are today. The doctrine of informed consent was in its infancy when the Beecher article was published and had only gained general acceptance by the time of the passage of the National Research Act. The *Belmont Report* was written against a backdrop of what was widely perceived as insufficient protection for human subjects, which was without doubt heavily influenced by the Nazi abuses in human subject research[16] and, closer to home, the lack of sufficient disclosure in the well-publicized Tuskegee experiments.[17] In reaction to these events, the field of bioethics developed three central guiding principles which are fundamental to the endorsement of stringent IRB procedures found in the *Belmont Report*. The gaps in that argument are instructive and deserve at least some mention.

The *Report* begins with the assumption of a sharp division between basic research on the one hand and practice on the other. Practice, even if it involves experimental or risky procedures, is in general for the benefit of the patient. "By contrast, 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)."[18] The clear inference here is that the duties on researchers are higher because the work is done for their benefit. The difficulty with the proposition is that it presupposes a level of detached generosity to explain why people participate in the studies, which in turn is said to require a greater level of protection. Yet there is little reason to think that most patients who enroll in these studies have that measure of detached generosity. The better evidence suggests that self-interest, not altruism, is the distinctive force.[19] Often the traditional programs have failed them, and participation in clinical trials may be their last possible hope. It seems better therefore to evaluate the participation in these programs wholly without regard to the distinction between practice and research.

What might those uniform norms be? The obvious ones are those which required informed consent for participation. In dealing with this issue, the *Belmont Report* followed the orthodox view of the basic ethical principles that should guide clinical research, all of which are applicable, to a greater or lesser extent, to ordinary medical care. At one level the *Report* speaks about the importance of the grand sounding "respect for persons," which is innocuous enough insofar as it stresses freedom from external pressures and special protection for incompetents. Thereafter the *Belmont Report* takes a somewhat more authoritarian tone when it writes: "In most

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[16] For one recent discussion, see Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. CIN. L. REV. 941, 951–52 (2006).

[17] *See* Charrow, *supra* note 1, at 710.

[18] BELMONT REPORT, *supra* note 14, at 3.

[19] *See* JERRY MENIKOFF, WHAT THE DOCTOR DIDN'T SAY: THE HIDDEN TRUTH ABOUT MEDICAL RESEARCH 4–6 (2006).

cases of research involving human subjects, respect for persons *demands* that subjects enter into the research voluntarily and with adequate information."[20] Thereafter it immediately veers off into the hard question of whether prisoners should be allowed to participate in clinical trials. But its one suggestive omission is that the *Report* never asks whether any research participant, like any ordinary patient, is entitled to waive the normal protections associated with informed consent, which would be required by any model that fully respects freedom of choice. More specifically, the word "waiver" is not used, even if the phrase "respect for persons" is. But the latter without the former is always a hollow invocation, especially since the term "demand" in the quoted sentence suggests a more authoritarian tone. Nonetheless, if the analysis in the *Belmont Report* stopped here, we could make a credible case that the function of the IRBs was only to collect information that allowed it to act as a surrogate for ordinary individuals who did not have sufficient time or expertise to make their own decisions.

At this point, however, the substitute of a publicly appointed third party raises serious questions for the general paradigm of liberty. The standard rule on third-party intervention is that individual family members and guardians make the choices on participation when the patient is unable to do that by him or herself. This translates into parents taking charge of children, spouses taking care of each other, and, most importantly, the widespread use of living wills and durable powers of attorney to take over in cases where patient competence is in question. The great advantage of this cluster of practices is that it chooses decision makers who are closest to the patients involved in either research or practice to make the decisions for them. The decisions therefore are necessarily done on a noncollective basis. Consistent with these clusters of practices, if some IRB recommended against the participation in certain trials, the family representatives should be entitled to reject that determination either on their own accord or after receiving advice from others. The logic of informed consent therefore seeks to use a decentralized system to honor the lofty sounding principle of "respect for persons." If this principle was actually followed, the IRB would become a bulletin board, not a regulator.

The latent authoritarian bias in the *Belmont Report* becomes ever more clear from its peculiar definition of beneficence. The *Report* writes that the ordinary definition of beneficence

> cover[s] acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.[21]

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[20] BELMONT REPORT, *supra* note 14, at 6 (emphasis added).

[21] *Id.* at 6.

The last sentence is a total non sequitur from the first because it abandons all pretense that the sole role of the state in these transactions is to give individuals the opportunity to receive information about the medical treatment. It is also a perversion of the ordinary meaning of the term, which stops with the idea of charity and goodness. Undeterred, however, the *Belmont Report* switches its focus from the choices of individuals to the entire structure of research programs by insisting that these programs be subjected to rigorous examination, both internal and external:

> The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.[22]

At this point, communication of accurate information is no longer the dominant issue. Rather, there is an independent duty, wholly unconnected to patient choice, to maximize benefits over costs. In one sense this could be regarded as a warm embrace of the usual collective utilitarian calculus which defenders of individual autonomy (at least some defenders) oppose. I believe that this tension between individual autonomy and the collective good is on balance overrated because the ability of informed individuals to follow their own best judgment is normally the best way to insure the excess of benefit over burden. But the *Belmont Report* is now in full pursuit of its regulatory mandate when it offers its account of the risk–benefit analysis that it regards as a moral imperative.[23] It notes that benefit is not a probabilistic term, but that in contrast, risk could cover either the chance of an adverse event, or its expected severity (probability multiplied by severity). The point is only of terminological consequence, for it is possible to create parity by using expected values on both sides of the equation. All it takes is substituting the phrase cost–benefit (or harm–benefit) for risk–benefit.

Finally, the third principle of ethics is that of justice, which refers to the fair distribution of benefits and burdens.[24] But the discussion here is inconclusive, and tends to restate the concerns raised in the section of the *Report* that analyzes the other two principles of ethics—the respect for persons and beneficence. The real action lies with the special definition of beneficence, which in turn gives rise to the asymmetrical weighting of harms and benefits that the *Report* embraces, without elaboration:

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[22] *Id.* at 7.

[23] *Id.* at 14–18.

[24] *Id.* at 8–10.

> Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.
>
> Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.[25]

I quote this passage at some length because it leaves open the question of the relative weight that should be attached to the costs and benefits of these projects. The one point that is clear is that the definition of harm that the IRBs should take into account is quite broad and confidently asserted. The offsetting social benefits are regarded as more diffuse, and there is little doubt that the remainder of the *Report* says nothing about the huge social benefits that could arise from the introduction of some new technique or drug. The *Report*, however, continues to express huge amounts of concern for the downside associated with these risks. "When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject—or, in some rare cases, to the manifest voluntariness of the participation)."[26] What is notable is that this sentence is the first one to insist, but without explanation, why the needed harm–benefit analysis becomes the appropriate fodder for a review committee, one whose natural inclination is to resist the protocols in question. The transformation is quite extraordinary. In three easy steps with a bunch of subordinate moves, the initial concern with freedom and choice is transmuted into a huge system of direct state regulation that leads to the kinds of abuses reported in the other papers in this study.

IV. BACK TO INFORMATION

How then does one try to deal with this explosion of regulatory power over research in both the biomedical and behavioral sciences? The most

[25] *Id.* at 15–16.

[26] *Id.* at 17.

obvious suggestion, which has been adopted in some places, is to uncouple the two forms of inquiry on the ground that medical research presents a far greater risk to human subjects than behavioral research.[27] I think that these proposals are welcome as far as they go. But they do not go far enough because they do nothing to challenge the coercive nature of IRB decisions. In the alternative, therefore, I think that a more far-ranging reform should be put on the table, one that seeks to respect the decentralized model of decision that is most consistent with the principles of individual autonomy and self-control.

In order to do this, I think that it is imperative to recognize that the explosion of information access utterly falsifies the assumption that all individuals need some collective surrogate to make their decisions for them. The key then is to find ways for the IRB to help form individual choices without dictating from the center that certain studies never see the light of day. One way to do this is as follows: The only requirement that is fixed for any research protocol is that it be published on some website to which all potential participants are referred before they are allowed to appear in the study. The IRB is then allowed to offer its criticisms and comments on the website for all individuals to read. There are no limits to the postings that it can make. It is, for example, fair game for it to say that its members unanimously regard it foolish for any individual to participate in the study. That power should certainly deter key researchers from putting forward plans that attract that kind of official wrath. But there is a further kicker as well. The IRB does not have the sole right to make comments. Any person can in an appropriate place add his or her comments to the general mix. These can take after the IRB or the study, or both. This dialogue could continue for some minimum period, say one month after the IRB has had its chance to look at the protocols and before the actual study begins. At this point, in the absence of fraud (which is highly unlikely given the multiple sources of information), any person who participates in the study does so at his or her own risk, so long as the study itself conforms to the original protocol. At this point we do have decentralized judgments and effective ways to promote the collection and organization of information. It is also possible for private individuals who don't understand these studies to get assistance from physicians, friends, and others who do. I have little doubt that the outcome of this procedure would in fact show a very different response to behavioral and biomedical research. Few people would hesitate long over the former, and those who do would be entirely within their rights. Institutions themselves should, of course, have the right to decide whether to devote their resources to particular programs. My fear is that they will do this unless they are given ironclad waivers against suits for programs that meet with their announced protocols. But if universities decide, without government pressure, to limit certain programs, then that is their choice,

[27] *See, e.g.*, Carpenter, *supra* note 1, at 701.

which should be respected. We will in any event get an accurate read as to the intensity of the preferences, for within universities the clinical investigators may well put substantial pressure on administrators to allow the programs to go forward so long as the contractual protection is provided.

CONCLUSION: A NEW CENTER OF GRAVITY

The approach suggested above is meant to shift power away from IRBs and towards individuals. The struggle over this transformation is likely to be tense, but such is an inescapable state of affairs when the stakes are high and the uncertainty great. Advocates on both sides have to recognize that there is no ideal solution to this problem. All that can be said with confidence is that we are likely to move the needle a little bit towards further liberalization of experimental protocols if the government thumb is off the scale. There is surely some good reason to fine-tune this or any other reform proposal. But we will continue to see horrid results in any area in which information is subject to the control of a state monopoly. As all friends of liberty know, decentralization of decision-making authority is the key to the success of their program. Unfortunately, the powers behind the IRBs understand this point every bit as well, which in a nutshell states the nub of the current agitation.