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REGULATING CREATIVITY: RESEARCH AND SURVIVAL IN THE IRB IRON CAGE[†]

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INTRODUCTION

When universities receive federal funding to conduct research, they make a number of promises to the U. S. Government. They promise, of course, to carry out a plan of research, and they promise to do so in a fiscally responsible manner. When the research involves human subjects, they also promise to ensure that the rights and welfare of human subjects who participate in this research are adequately protected through an Institutional

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Review Board ("IRB") mechanism. IRB review is a requirement of a university's Federal-Wide Assurance ("FWA") contract with the government,[1] which binds it to administer any federal research funds it receives by federally mandated standards. At first glance it seems self-evident that institutional efforts to protect human subjects in compliance with these regulations can only be a good thing. At most universities, however, the reach of the IRB mission as well as its bureaucracy has now superseded by far the visions of the designers. Universities in the United States are replete with regulatory systems and bureaucracies, covering everything from grant accounting and accreditation to fire codes.[2] Among them, however, the IRB system is the only one that has the direct power to stop, delay, or change the character of research, the most prized product in the university system. IRBs have disrupted student careers, set back tenure clocks, and blunted the essence of many intellectual traditions. Facing demands that spiral to the level of sheer impracticality, faculty and students at many institutions face a stark choice: to conduct innovative research in their fields or to meet the requirements of their institutions' IRBs.

Nor is there any persuasive evidence that research subjects' rights or welfare have benefited, overall, in exchange for this damage. From our own experience, which we document below, we know that there are specific instances in which IRB panel members spot potential risks for subjects that are overlooked by investigators. Since no other research regulatory system in history has ever approached the U.S. IRB system in scale or in the kinds of demands it makes, however, meaningful controlled comparisons are out of the question. Indeed, as far as we know, no credible assessments have been conducted that could determine whether IRB review actually protects people or in what ways.

The specter of IRB sanction pervades all that students and faculty do in fields deemed to be IRB-relevant. IRB offices are the institutional executors of concern for human research subjects by the U.S. government, the financial lifeblood of most universities. Yet in enacting what they see as their responsibility of ethical oversight of research, they affect everything from imagining a study's scope and significance to the choice of words in a survey. It is little wonder that many researchers, fearing not just obstacles to their own research but the suspension of all federal funding to their university, appear to lead lives either of resentful compliance with IRB or of fearful avoidance of it.

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[1] *See generally* United States Department of Health and Human Services, Human Research Protections Database, http://ohrp.cit.nih.gov/search/asearch.asp (last visited Nov. 10, 2006) (providing a list of approved assurances and related information).

[2] *See, e.g.*, University of Kentucky Regulations, http://www.uky.edu/Regs/ (last visited Nov. 10, 2006). (The University of Kentucky's page on university regulations shows how a search of any university's web site quickly reveals the great number of such regulations. It has a list of twenty-eight links, each to a separate area of university regulations, spanning such things as "Administrative Regulations" as well as "Bicycle Regulations.").

The purview of IRB control has expanded broadly as well as deeply. IRB has been generalized from the medical world to a wide range of social science and, in some cases, humanities research.[3] The major American professional scholarly associations, in their ethics statements, tend to urge their members to obtain IRB approval as a matter of professional ethics.[4] Although most approved FWAs are in the U.S., IRBs have inserted themselves into the research codes of one or more institutions in nearly all countries in the world.[5] And although most educational institutions with IRBs are universities or medical research organizations, a growing number of high schools, though they do not appear to have formal FWAs, have been drawn into IRB requirements,[6] or at least the language of IRB compliance, through an organization called Science Service, which sponsors the International Science and Engineering Fair program.[7] Several elementary schools, in fact, have linked their science fairs to IRB rules through the same Science Service portal.[8] IRB obligations now appear to be incumbent even on kindergartener science fair participants in one ambitious school district in Tennessee.[9]

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[3] *See, e.g.*, Christopher Shea, *Don't Talk to the Humans: The Crackdown on Social Science Research*, LINGUA FRANCA: THE REVIEW OF ACADEMIC LIFE, Sept. 2000, at 27, 29; Emory University, Human Subjects and the Humanities, http://www.emory.edu/ACAD_EXCHANGE/2002/aprmay/humsubj.html (last visited Nov. 10, 2006); University of North Carolina, Human Research Ethics, http://ohre.unc.edu/ (last visited Nov. 10, 2006); University of Illinois at Chicago, Institute for the Humanities, http://www.uic.edu/depts/huminst/ovcr-aah/guidelines.html (last visited Nov. 10, 2006).

[4] *See, e.g.*, AMERICAN PSYCHOLOGICAL ASSOCIATION, ETHICAL PRINCIPLES OF PSYCHOLOGISTS AND CODE OF CONDUCT § 8.01 (2002), *available at* http://www.apa.org/ethics/code2002.pdf.

[5] *See* Office for Human Research Protections, International Assurances ("FWA") by Location, http://ohrp.cit.nih.gov/search/actrypck.asp (last visited Nov. 10, 2006). Based on personal correspondence with Jonathan Knight of the American Association of University Professors ("AAUP"), it seems reasonable to believe that, worldwide, there are now over 7000 FWA agreements between individual institutions and the U.S. government.

[6] Students Dan Montgomery and Sam Lim first drew this to our attention, recounting their own IRB experience at the Illinois Mathematics and Science Academy.

[7] Science Service, Background, http://www.sciserv.org/isef/about/background.asp (last visited Nov. 10, 2006). The International Science and Engineering Fair (ISEF) is under the auspices of "Science Service," which issues guidelines for local science fairs that seek affiliation with it, and for the students, teachers, and judges who participate in them. *See* SCIENCE SERVICE, INTERNATIONAL RULES FOR PRECOLLEGE RESEARCH: GUIDELINES FOR SCIENCE AND ENGINEERING FAIRS 12–14 (2006).

[8] *See, e.g.*, Discovery School, *Before You Begin Section*, http://school.discovery.com/sciencefaircentral/dysc/tips/tips.html (last visited Nov. 10, 2006) (providing links to Science Serve, Affiliated Fairs, http://www.sciserv.org/dcysc/fairs/fairlist.asp).

[9] Guidelines for the Clarksville–Montgomery County Schools Science Fair 4 (2006), http://www.apsu.edu/robertsonr/sciencefair/2006%20COMPLETE%20SCIENCE%20FAIR%20MANUAL.doc (last visited Nov. 10, 2006). Aside from science fair participation, the rationale for extending IRB rules to pre-college schools is unclear. These schools may have been drawn in by a combination of convenience and academic aura—a ready-made, standardized package of rules used by universities. Alternatively, their adoption of IRB culture may have arisen from the entry into professional life of new cohorts of high school teachers who have been imprinted with IRB experience in their own training.

Predictably, faculty objections to the tightening grip of IRBs on research have escalated.[10] Recently, a serious First Amendment question has emerged as well: that of censorship.[11] Censorship refers to the act of inspecting some form of expression—anything from a scientific finding or a political opinion to a work of art—in order to suppress or delete elements alleged to be harmful, offensive, or immoral.[12] Given the limits of our own expertise, we cannot conclude that IRBs' rules or practices constitute censorship in the most technical constitutional sense. What is clear to us is that IRB review strikes to the core of the research enterprise. To the extent that investigators attempt to stick to certain pathways of allowable conduct to create a protocol that will pass regulatory muster, the IRB is also aligned with the concept of advance permission, the foundational notion of censorship, or obstructing the freedom of expression. In fact, as we will show, it goes beyond, comprising a case of what Emerson's classic analysis might see as attempting to disrupt the very actions required to compile an opinion to express.[13] This the IRB does according to criteria that explicitly begin not from any claimed social-good tradeoffs that might justify the quashing of free speech, but simply from the kind of information that is being produced: research.

The hand of IRBs has been felt heavily in both the social and biomedical sciences. Nonetheless, there are striking inequities. For example, at Northwestern, the volume of biomedical proposals submitted to the IRB is much greater than that of social science proposals. However, social science researchers tend to have less assistance than biomedical researchers for generating IRB protocols and keeping track of the voluminous documentation that each protocol can create.[14] More problematically, as we will explain, social science research paradigms fit poorly into the thrust of

[10] *See, e.g.*, *Protecting Human Beings: Institutional Review Boards and Social Science Research*, ACADEME, May–June 2001, at 55; *For the Record: Should All Disciplines Be Subject to the Common Rule? Human Subjects of Social Science Research*, ACADEME, May–June 2002, at 62; *Research on Human Subjects: Academic Freedom and the Institutional Review Board*, ACADEME, Sept.–Oct. 2006, at 95; Charles L. Bosk & Raymond G. De Vries, *Bureaucracies of Mass Deception: Institutional Review Boards and the Ethics of Ethnographic Research*, 595 ANNALS AM. ACAD. POL. & SOC. SCI. 249, 249 (2004); James Boster, *Towards IRB Reform*, ANTHROPOLOGY NEWS, May 2006, at 21; Richard A. Shweder, *Protecting Human Subjects and Preserving Academic Freedom: Prospects at the University of Chicago*, 33 AM. ETHNOLOGIST 507 (2006).

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

[12] *See* Thomas I. Emerson, *Toward a General Theory of the First Amendment*, 72 YALE L.J. 877, 880 (1963).

[13] *Id*. at 881–82.

[14] In personal correspondence with Don Workman, the Executive Director of the Office for the Protection of Research Subjects at Northwestern, he has pointed out that the institutional focus on the "high-risk" biomedical research does not only disenfranchise the social scientist. Whole colleges and the great bulk of the undergraduate population whose universities accept federal money may face IRB burdens of time and effort reporting requirements as well as research integrity efforts, without themselves receiving direct benefit.

medically-driven IRB protocol templates and language. Though the evidence we have amassed has suggested that IRB demands have wreaked more damage on social science than on biomedicine, the biomedical IRB story, on which we have much more sketchy evidence, may be even more interesting.

Whether one looks at the United States or abroad, up or down the educational pyramid, or across the disciplines, the singular impact of the IRB on recent U.S. academic history cannot be understated. All this raises two obvious questions: (1) How, in the face of this tightening regulatory vise, has research, particularly social science research, survived at all? And, (2) how has it changed in order to do so? Our scope is restricted largely to the social sciences, though IRB attempts to regulate biomedicine in recent years are central to the social science story.

We first sketch the history of the U.S. IRB system and its penetration into local institutions. With an eye to the core concepts that underlie IRB purview ("risk," "research," "regulation," and "compliance"), we outline some key works in organization theory (classic and popular) that illuminate the continuing growth of the IRB nationwide and its intensifying efforts to develop techniques to preempt risk. We then turn to the pragmatic responses these trends have produced in research universities: how local players have begun to incorporate the regulatory demands into their thinking and practice. We focus on responses that we call "deterrence," resulting in chilling and distortion of research. We also highlight responses we call "consensual censorship" among researchers as well as IRB representatives who, from their structurally antagonistic positions, develop unspoken working understandings and pursue collective agendas of collusion that result in what IRBs can then call compliance. Such collective constructions of language and practices to create pathways through the otherwise-impossible review hurdles, we believe, are the key factor that has kept U.S. social science research alive in the era of IRB ramp-up. Describing the models that result, we reflect on the deep systemic changes in scholarship and teaching that the institution appears to be generating. Our focus on the players—researchers, students, and IRB representatives—thus becomes a window into the rise of an entirely new configuration by which creativity itself becomes regulated.

Trying to unravel the mystery of the social sciences' survival in the face of IRB encroachment is a challenge replete with paradoxes and illusions. The exercise demands that we probe the convergent logics of two mutually exclusive things that must somehow co-exist: creativity and regulation. It also requires that we treat the IRB organization not as an infallible pillar of moral authority but as a social institution like any other. The odd history of IRB and its effects have been no one's fault; no one's intention. No convenient villains or victims emerge anywhere we look. Indeed, we will suggest that, by necessity, social scientists themselves have been re-

cruited to create legal rituals of controlling risks that hardly exist, in order to show that they are properly regulated.

Two major and several subsidiary qualifications must be established. First, most of us do not speak as legal experts. We speak instead from our experiences as researchers and IRB representatives. Nearly all of us have had experience with the IRB as investigators. We also draw on information stemming from our recent work on a subcommittee of the Northwestern University IRB Advisory Committee (chaired by Bledsoe), on which we all served. Besides these roles, Sherin has served on an IRB panel at Northwestern University for more than nine years and has been chair of the panel that reviews social science research for the last four years, while Roloff has served from 1994 to 1998 and from 2000 to the present, and Bledsoe served from 2000 through 2003 as a member. In addition, Headley and Kjeldgaard have been staff members at Northwestern's IRB, Heimer is the current chair of the American Bar Foundation's IRB, and Miller served as the head of the Northern Illinois University IRB. Among us, we have known about hundreds of cases, and we have listened to the same number of IRB concerns from colleagues and students at our institution and elsewhere in the U.S. These experiences of trying to reconcile IRB policies with other aspects of our professional lives, together with the roles that most of us have had as agents of Northwestern's IRB and as mentors and colleagues of researchers who must pass through its filters, have led us to this inquiry into the logic and institutional growth of IRB.

The second qualification is that any attempt to talk about IRB review as a unitary phenomenon or to compare the effects of IRB review on research and teaching practice across institutions necessarily oversimplifies. Among IRB organizations, change is the rule rather than the exception. Thus, the challenge we face is to try to pin down a moving target, and not just one of them, but a dizzying array of local IRB cultures that arise from idiosyncratic mixtures of national events, university policies, administrative philosophies, disciplinary variations, and a history of local cases. Rotating and accreting personnel, forms, and policies, an IRB organization is in constant motion. This character of flux itself raises many questions, particularly, since compliance is the institution's central concern, that of, "Compliance with what?" We have some knowledge of the IRB situations at other U.S. institutions.[15] Our safest statements about the effects of IRB,

[15] The AAUP has produced two general statements on IRBs (in 2001 and 2006). *Protecting Human Beings*, *supra* note 10; *Research on Human Subjects*, *supra* note 10. For a discussion on the appropriateness of IRB oversight in the social sciences, see also *Should All Disciplines Be Subject to the Common Rule?*, *supra* note 10. There are undoubtedly a number of reviews of university IRBs that include faculty members as members of standard university review cycle teams, but these are seldom made public. An ad hoc committee at the University of Arizona conducted by five anthropologists produced a report on the University of Arizona that was made available to us. Rhonda Gillett-Netting et al., Review and Approval of Human Subjects-Related Research at the University of Arizona: A Critical Assessment

however, are limited largely to a historical treatment of events at Northwestern, our point of common institutional experience, and to comparisons among the units presently within them. What this also means, of course, is that our own IRBs' changes will inevitably make this article dated almost as soon as it is published, hopefully in ways that will represent improvement. In this event, this article may serve as a historical record of one university's struggles with a moral ideology laid atop what effectively become competing goals of research and regulation.

I. HISTORY: BUILDING A REGULATORY BUREAUCRACY

Just as there is enormous variation among contemporary U.S. institutions regarding their IRB regimes, there has been possibly even greater variation across time in U.S. government regulatory practices themselves. How have IRB rules at the national level come to constitute the peculiar structure that we now see? Answering this question will both set the stage for understanding the structure and dynamics of the organizations that surround IRBs, and provide the basis for our subsequent considerations of impact and response.

A. The Origins of Federal Regulation of Research Involving Human Subjects

The regulatory architecture underlying the protection of human research subjects in the United States is set out in 45 C.F.R. § 46, the Code of Federal Regulations Governing the Protection of Human Subjects in Research.[16] These regulations drew on lessons of history derived from experiences such as the Holocaust and the syphilis study at Tuskegee.[17] They also drew inspiration from the 1947 Nuremberg Code governing human medical

(2003) (unpublished report, on file with the University of Arizona); *see also* Shweder, *supra* note 10 (describing the current situation at the University of Chicago).

[16] Subpart A of 45 C.F.R. § 46 (2005) is often referred to as the "Common Rule." It was so named because it was generalized to all relevant government agencies sponsoring human subjects research that have signed and endorsed it. The most recent agency to do so was—perhaps most incongruously, because of its association with militarism—the Department of Homeland Security. *See, e.g.*, DEP'T OF HOMELAND SEC., BOARD AGENCY ANNOUNCEMENT 21 (June 18, 2004), *available at* http://www.dhs.gov/xlibrary/assets/S_T_BAA06July2004.pdf. For a general history of human subjects review in the United States, see Laura Jeanine Morris Stark, Morality in Science: How Research Is Evaluated in the Age of Human Subjects Regulation 23–127 (Nov. 2006) (unpublished Ph.D. dissertation, Princeton University) (on file with author).

[17] *See, e.g.*, JAMES H. JONES, THE TUSKEGEE SYPHILIS EXPERIMENT (1993); *see also* National Center for Juvenile Justice, The Juvenile Justice Professional's Guide to Human Subjects Protection and the IRB Process: What We've Learned from History, http://ncjj.servehttp.com/irb/History.asp (last visited Nov. 10, 2006); Office of the Vice President for Research, University of Minnesota, Teaching Ethics for Research, Scholarship, & Practice, http://www.research.umn.edu/ethics/curriculum/human_subjects.html#History (last visited Nov. 10, 2006).

experimentation[18] and the 1964 Helsinki Declaration governing biomedical research on human subjects.[19] By far the most important influence on this regulatory framework, however, was the document that came to be called the *Belmont Report* of 1979.[20] Commissioned by the U.S. Department of Health, Education and Welfare (later called the Department of Health and Human Services ("HHS")), the *Belmont Report* proposed guidelines for the ethical treatment of human research subjects. Building on the history of Western ethical thought, it centered on principles of respect, beneficence, and justice, and targeted three specific areas for evaluating human subjects research: informed consent, risk-benefit assessment, and equitability of subject selection.

These regulations, links to which can be found on every U.S. university's website,[21] required entities that sponsor federally supported research involving human subjects to establish IRBs to approve research involving human subjects before this research may go forward.[22] Once it was determined that research should be regulated, the next question was what activities, specifically, lay within this regulatory purview. The regulations provide the following definition:

> *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.[23]

The Code also sets a number of other structures. It establishes categories of risk for which different types of review are required.[24] Projects with the highest level of assessed risk can only be considered by a convened panel of IRB members.[25] Exempted projects, with little or no risk, can be evaluated outside a convened meeting, as can expedited projects, with no more than minimal risk, and both allow the exercise of IRB authority by a single reviewer though the panel must be informed of expedited approvals; exempted projects, with little or no risk, can be evaluated outside a con-

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[18] 2 U.S. GOV'T PRINTING OFFICE, TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181–82 (1949).

[19] WORLD MEDICAL ASSOCIATION, DECLARATION OF HELSINKI (1964), *available at* http://www.wma.net/e/policy/b3.htm.

[20] THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, 44 Fed. Reg. 23,192 (Apr. 18, 1979).

[21] *See, e.g.*, Harvard School of Public Health, Human Subjects Committee, http://www.hsph.harvard.edu/hsc/links.html (last visited Nov. 10, 2006); Northwestern University, Institutional Review Board, http://www.research.northwestern.edu/research/oprs/irb/resources/ (last visited Nov. 10, 2006).

[22] 45 C.F.R. § 46.103 (2005).

[23] 45 C.F.R. § 46.102(d) (2005).

[24] 45 C.F.R. § 46.109(e) (2005).

[25] 45 C.F.R. § 46.108 (2005).

vened meeting.[26] Both "full" and expedited review projects are required to be renewed annually; exempt projects are not.

With the *Belmont Report*'s medical origins and the close linkage between federal legislative intent and the mission of the National Institutes of Health ("NIH"), the authority for administering the IRB mechanism was given an institutional home in the NIH. The legislative hearings and debate had expressed a desire for the institutions doing biomedical research to develop their own institutional procedures to implement the general framework, an approach that the academic community supported. To allow scope for locally specific strategies for implementing the regulation as well as to avoid creating a centralized bureaucracy, legislators placed the primary review function at the local institutional level. Each institution would have its own review boards containing experts on the subject matter at hand[27] who could judge the risks a study was likely to generate and advise on proactive protections. Though the composition has varied within universities, IRBs have commonly been composed of faculty members, administrative staff, and community members from whose ranks study populations may be drawn.

B. NIH Carrots and Sticks

Developing alongside the federal IRB regulations was a growing financial incentive. Since the 1980s, the NIH budget had grown slowly but steadily. In the late 1990s, a pro-science Democratic U.S. administration, seeking international leadership in pathbreaking science such as the Human Genome Project and stem cell research, pledged to double the NIH budget over the next five years. Beginning at $13,647,843,000 in 1998, NIH funding rose steadily to $27,066,782,000 in 2003.[28] The chart below, showing funding figures, does not adjust for inflation and reflects a changing corpus of recipient agencies. Still, the main trends are unmistakable: a slow increase over two decades, a five-year doubling surge between 1998 and 2003, and then an abrupt flattening.[29] For 2006, the NIH appropriation leaves a budget of $28.6 billion, down 0.1% from 2005: the first budgetary cut for the NIH since 1970. After adjusting for inflation, the NIH budget is smaller in 2006 than in 2003.[30]

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[26] 45 C.F.R. § 46.101(b) (2005); 45 C.F.R. § 46.110(b) (2005).

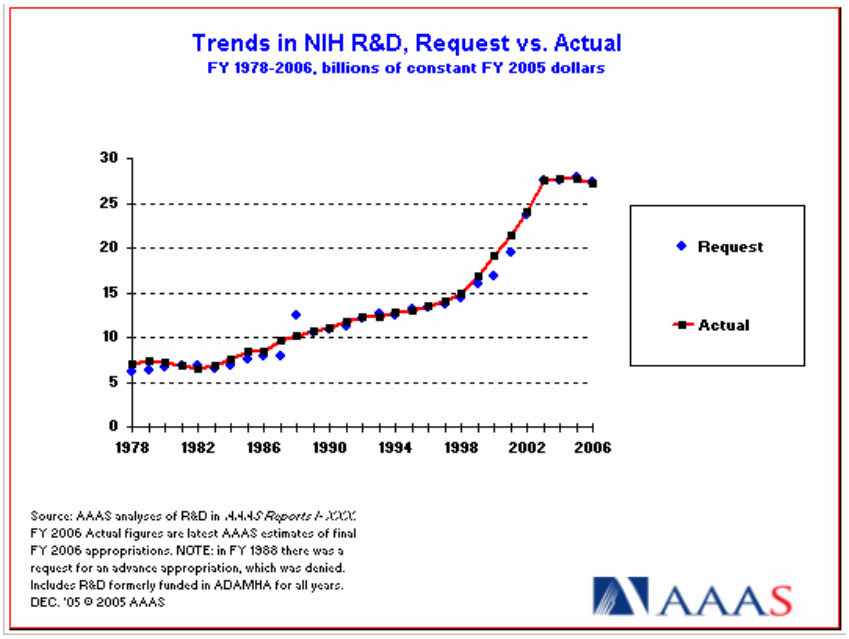
[27] 45 C.F.R. § 46.107 (2005).

[28] National Institutes of Health, Appropriations, http://www.nih.gov/about/almanac/appropriations/part2.htm (last visited Nov. 10, 2006).

[29] This last feature seems even more significant, given that there is no adjustment for inflation.

[30] American Association for the Advancement of Science, Funding Update on NIH R&D Spending for 2006, http://www.aaas.org/spp/rd/nih06f.htm (last visited Nov. 10, 2006).

Figure 1



Source: http://www.aaas.org/spp/rd/nih06f.htm

According to a professional with national experience in academic administration placement, the response to the surge between 1998 and 2003 was immediate.[31] Cash-strapped universities turned to NIH for their overall operating costs, going in many cases far beyond their base in tuition and endowment.[32] At the same time, however, universities faced belt-tightening demands. NIH began to ban allowances on indirect cost recovery and to cap salaries and tuition payments in training awards.[33] By 2003, the doubling phase had ended. With the repercussions of the September 11, 2001, World Trade Center attacks settling in and the federal budget now in deficit, the fiscal priorities of the Bush administration shifted away from health research. The huge increase in NIH funding coupled with its recent decline left many universities in financial limbo, wondering how to fund new programs and facilities they constructed during the boom.[34]

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[31] This connection was noted by a knowledgeable source who asked not to be cited directly.

[32] *See* David Korn et al., *The NIH Budget in the "Postdoubling" Era*, 296 SCI. 1401 (2002).

[33] *Id.* at 1401.

[34] Recent NIH budgets have reflected even more strongly the sag in Bush administration health priorities. While the biodefense level for 2006 is at the same $1.75 billion level of the 2003 NIH package, much initial building infrastructure investment is now completed, meaning that funding for biodefense research itself has increased, one of the few areas of NIH funding that has done so. American Association for the Advancement of Science, *supra* note 30. According to some observers, the effects of the 1998–2003 doubling phase will be lost altogether by 2007. *See* Office of Public Affairs, Chart on

Alongside the financial expansion, the human subjects office of the NIH expanded both its reach and the corpus of rules governing research. Known initially as the Office for the Protection from Research Risks ("OPRR"), it expanded in size and elaborated the scope of its mission. In 2001, it became independent of the NIH, becoming an independent regulating authority within HHS and changing its name to the Office of Human Research Protections ("OHRP"). If in trouble with OHRP, the various governmental signatories to its regulations may withhold funds from grantee institutions, as might other funders.

The original legislation had not given OPRR the power to issue regulations, but the office began to issue guidelines intended to amplify and clarify the original regulations, though these guidelines lacked the standing of regulations codified through the Federal Register. Staff also began to respond in case law fashion to each problem that arose in any field and in any institution, using each devised solution as the basis of new rules to generalize across the board. Adding to the accumulating corpus of rules was the impact of several high-profile legal cases concerning alleged harms to research subjects. Roughly contemporaneous with the spike in NIH funding, several cases of injury and death stemming from medical studies drew national attention. In the late 1990s, the NIH office overseeing research on human subjects gained new authority to halt funding to institutions for suspected breaches of compliance.[35] NIH proceeded in short order to suspend federal funding of several institutions, including Duke University Medical Center, the University of Illinois at Chicago, and Virginia Commonwealth University.[36] By taking an assertive stance in regulating research through local IRB policies and practices, the federal government served notice to all research institutions that they should take a hard look at their regulatory practices. As it did so, it fueled a nation-wide climate of anxiety among university administrators.

The close temporal sequencing of the expansions in both the NIH budget and the IRB regulatory mission raises unavoidable questions of causation. Did the acquisition of more fiscal muscle embolden OHRP to make more regulatory demands on universities? Conversely, did the lure of money make universities reluctant to raise questions about the academic costs of toeing the regulatory line? And, most troubling, did the NIH funding increases have the perverse effect of damaging research rather than enhancing it? Certainly, the more that universities are dependent on federal

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Budget Gains from NIH Doubling, http://opa.faseb.org/pdf/DoublingEliminationChart.pdf (last visited Nov. 10, 2006).

[35] Shea, *supra* note 3, at 28.

[36] *Id*. For more general information, see OHRP's instructions for reporting "unanticipated problems involving risks to subjects or others," "serious or continuing non-compliance with DHHS . . . or IRB," and "suspension or termination of IRB approval." Office of Human Research Protections, Department of Health and Human Services, Guidance on Reporting Incidents to OHRP (May 27, 2005), *available at* http://www.hhs.gov/ohrp/policy/procedures_for_reporting_052505.pdf.

funding, the more they are vulnerable to whatever demands OHRP can make, regardless of their advisory or guideline status. University IRB policies have become so inflated in the wake of these events that it is hard to avoid the speculation that the expansion of IRB review was driven more by anxiety about losing NIH bounty than by concerns about human subject abuses. The fact there are no reports of increasing harm by social science research procedures over time suggests that real dangers to human subjects cannot explain the regulatory surges.

II. REGULATING CREATIVITY

We have no evidence at all to suggest that any IRB anywhere has sought systematically to suppress research. Inevitably, however, the relationship between any regulatory agency and the entities it regulates is fraught with tension, and, in the case of the IRB, we believe that this tension has been especially damaging to research, the object of its regulatory energies. A university's mission is to produce new knowledge. As a concomitant, the university must allow researchers the latitude to explore and to be open to serendipity, a freedom that has held the key to great discoveries. Required is a search for unknown configurations of elements and processes of transformation. All this is true especially of exploratory or open-ended research. Such research, beginning from the assumption that conventional ideas about the world may be misleading and that hence the best ideas come as surprises, depends on high degrees of freedom. A researcher whose inspiration comes explicitly from an inductive philosophy must be open to opportunistic streams of new ideas, whether they arise from direct observation, casual conversation, collaboration, reading, or the mining of large sets of numbers. To be open to novelty and anomaly, open-ended work must cast a broad methodological net. Questions that were not anticipated at the outset may suddenly take on pressing importance. Groups that initially seemed peripheral to a study can suddenly swerve to frontal attention. Further, the research question itself is expected to evolve through fits and starts during the course of the study. It could even do so several times within the course of one excellent interview.

In contrast with the mission of the university to create an environment that nourishes the free-flow of ideas in order to generate knowledge, the mission of the IRB is to regulate the production of knowledge by bringing it into alignment with federal rules and standards. The tension between IRB review and research that is most conducive to new discovery is obvious: an open-ended study, for example, could require new regulatory approvals each time the topic took a different turn. In disciplines that rely on open-ended approaches and fieldwork, good researchers are by definition "IRB outlaws."[37] For some fields, having constantly to traverse a field of IRB

[37] Jack Katz, *Ethical Routes for Underground Ethnographers*, 33 AM. ETHNOLOGIST 499, 500 (2006).

rules and risk categories—and a constantly shifting field at that—undermines their entire epistemology.

Clues to how creativity is undermined in a regulatory environment emerge in two very different source materials on organizations. To convey a sense of what kind of organization IRBs have become after NIH and OHRP so dramatically raised the compliance stakes, we start with an analogy from the field of accident and risk management. We follow up with some general works from the sociology of organization.

A. The Art of Pre-Emption in High-Risk Organizations

Complex organizations that must operate in environments where the smallest slip could bring catastrophic consequences are called "high-risk organizations" ("HROs"). Such organizations are classic case studies for students and practitioners in the field of accident and risk management.[38] In a how-to manual for managers, Weick and Sutcliffe use air traffic control systems and nuclear aircraft carriers as examples of HROs, which they more euphemistically call "high-reliability organizations."[39] Such organizations rarely experience disaster even though they operate under constant and extraordinary danger. Nuclear aircraft carriers, the most riveting example in the book, dominate the descriptions of Chapter 2, from which the following material is drawn.

Nuclear aircraft carrier vessels cram six thousand people into tight spaces far away from shore on a "95,000-ton floating city run by an overburdened 'mayor.'"[40] The basic job description of the commanders of such vessels is to move aircraft "off the pointed end" and back onto "the blunt end" of a surface that has been called "the most dangerous four and one-half acres in the world,"[41] and to do so at roughly 48 to 60 second intervals:

> This "acreage" is filled with up to eighty jet aircraft, some of which at any one time are being fueled with their engines running, or having armed lethal weapons attached to their wings, or being launched off the front of the ship by two million horsepower catapults that accelerate the 65,000 pound plane to 150

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[38] Other examples from the field of risk management include firefighting, now a cliché among managers; disaster planning; terrorism prevention; and insurance underwriting for hospitals. *See generally* CAROL A. HEIMER, REACTIVE RISK AND RATIONAL ACTION: MANAGING MORAL HAZARD IN INSURANCE CONTRACTS (1985) (providing a general social science treatment of the professionalization of risk); Marilyn Strathern, *Introduction, New Accountabilities*, *in* AUDIT CULTURES: ANTHROPOLOGICAL STUDIES IN ACCOUNTABILITY, ETHICS AND THE ACADEMY 1 (Marilyn Strathern ed., 2000) (providing analyses of attempts to monitor responsibility, ethics, and accountability).

[39] KARL E. WEICK & KATHLEEN M. SUTCLIFFE, MANAGING THE UNEXPECTED: ASSURING HIGH PERFORMANCE IN AN AGE OF COMPLEXITY 3 (2001).

[40] *Id*. at 27.

[41] *Id*. at 25.

> miles per hour in three seconds, or are being recovered simultaneously at the back end by what amounts to a "controlled crash."[42]

In an environment of capricious weather, tight budgets, slippery decks, and live weapons all around, officers must maintain in total readiness the raw materials of fickle technology, unreliable aircraft, and a crew made up largely of 19- and 20-year olds who find high-risk activity itself a form of entertainment. How, one might ask, do HROs manage?

HROs, explain Weick and Sutcliffe, are preoccupied with failure.[43] Reluctant to simplify, taking nothing for granted, their managers position themselves to command and monitor all operations. They launch nothing until lines of responsibility are fully in place and all parts and procedures have been checked by redundant inspections, and they draw up contingency plans in case of breaks that will allow them to contain the damage and to restore system functioning before it spreads. That anyone at all comes back alive from missions aboard nuclear aircraft carriers, Weick and Sutcliffe attribute largely to what they call the "mindfulness" that these organizations cultivate in order to "manage the unexpected" in an environment that assumes catastrophic failure.[44] That is, these organizations seek to pre-empt the unexpected through the art of anticipatory "sense-making" of materials in their earliest stage of formation. Scrutinizing pools of amorphous elements that lie as little more than suggestions, they search constantly for signs of potentially harmful emerging configurations. Spotting those with the remotest chance of causing harm, they take swift pre-emptive action to disrupt them in their unformed phases. By fine-tuning their ability to recognize "increasingly plausible interpretations" of the formative stages in which raw materials begin to coalesce, and interrupting pathways that can be plausibly interpreted as having potential harm just as they begin to emit "weak signals," HRO managers strive to sift out risk.[45] Their goal is to allow only those patterns to emerge that will produce safe, familiar outcomes.

IRB bureaucracies are hardly "high reliability" organizations. Unlike air traffic control or nuclear submarine navigation organizations, their day-to-day activities, beyond the immediate goal of following their own procedures, are vaguely defined. But the IRB's over-riding goal is clear: to avoid the enormous risk to the institution of being found in noncompliance by OHRP. IRBs thus share the ideology of HROs, in that they must see everything around them as potential source of catastrophic risk. Indeed, if operating a nuclear aircraft carrier in an environment with zero tolerance for accidents is difficult, attempting to regulate university research according to endless lists of obscure but nonetheless mandatory standards is arguably even more so, with crews of researchers who find IRB rules irrelevant ob-

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[42] *Id*. at 25–26.
[43] *Id*. at 10–11.
[44] *Id*. at 3.
[45] *Id*. at 4.

structions to their job descriptions and its stated ideals dubious. IRBs' methods are remarkably like those of HROs in their attempt to create wide margins of safety that allow "normal" activity and terminate activity that exposes the institution to lawsuits or, even worse, suspension of federal funding for non-compliance.

The problem, of course, is that the same ingredients that produce harm are also the only ones that can produce novelty, the *raison d'être* of a university. Seeking to create wide margins of risk by filtering out all but a few safe, predictable elements from a vast array of potentials, IRBs can thus disrupt the very stuff of creativity. In times of high vigilance, the effort to create safety margins by monitoring closely ambiguous elements, allowing the narrowest of pathways to guide their development and snuffing out the earliest signs of difference, effectively eliminates the possibility of novelty in these pathways altogether.

B. The Sociology of Bureaucracy

The rise of bureaucracies such as IRBs and their attempt to control multiple aspects of life was presaged a century ago by German sociologist Max Weber. Weber argued that organizations that begin modestly from ideals have the potential to transform through inexorable bureaucratization into legalistic monstrosities. Bureaucratic organization, he explained, is highly specialized, breaking down complex tasks for greater efficiency into manageable parts. Hierarchical chains of administrative officials direct behavior and exact compliance within clearly defined areas of responsibility, according to consistent, impartially applied sets of rules.[46] In *The Protestant Ethic and the Spirit of Capitalism*, the classic study of the bureaucratization of German society in the wake of the Industrial Revolution, Weber made a bleak prediction: bureaucracy, precisely because it was the most efficient form of organization, would eventually dominate modern life, rendering it sterile, with little scope for creativity or personal initiative. The relentless press of bureaucratic efficiency would ultimately replace ends with means, suppress spontaneity, and freeze individuals permanently into a rigid "iron cage" of rationality.[47]

The tradition that followed *The Protestant Ethic* and other seminal works by Weber has both extended and qualified his insights into organizations. Among the most notable of those he inspired was Robert Merton,

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[46] The evolution of voluntary compliance through "e-government" offers a striking parallel to the eIRB system that many universities are putting in place. Presenting itself as a trusted servant that seeks to improve efficiency and reduce administrative "nuisance," virtual government results in citizens willingly ceding their rights to privacy by allowing government to collect and retain data about every aspect of their lives. *See*, Giovanni Navarria, *E-Government: Who Controls the Controllers?*, OPEN DEMOCRACY, Feb. 9, 2006, http://www.opendemocracy.net/content/articles/PDF/3254.pdf.

[47] MAX WEBER, THE PROTESTANT ETHIC AND THE SPIRIT OF CAPITALISM 182 (Talcott Parsons trans., 1958) (1904).

who sought to clarify how, as Weber had observed, the rules and formalities by which a bureaucracy seeks to accomplish its ends can themselves become the ends.[48] Merton concluded that this process of "goal displacement" emerges when managers intentionally overestimate risk to create wide margins of safety in order to avoid inefficiency and avert costly accidents. Instituted as precautionary measures in the forms of additional rules and insistence on strict adherence to the formalized procedures of the organization, these margin-of-safety measures, originally intended to ensure that the organization's goals are met, become the overriding concern. Thus, bureaucratic officials are constantly engaged in attempting to "repair" instances of breakdown and to devise solutions to close discrepancies.[49] As the bureaucracy swells, its ranks fill with functionaries assigned first to create rules and then to create more rules to reduce the nuisance the initial rules have spawned. Moreover, these expanding compliance demands can inflate the costs of running its procedures to the point where most of its members opt out by reducing their productivity, leaving those who remain committed to the goals for which they were hired at risk of being declared noncompliant.[50]

The IRB institution that most of U.S. academia has come to know is an archetypal "iron cage." It attempts to control each step of a research protocol, it constantly expands rather than contracts its mission, and it deals uneasily with novelty. It places enormous emphasis on the notion of compliance, which it casts in absolutist terms: there is either compliance or noncompliance, with little between. Compliance is also an inclusive state. The slightest infraction—a misplaced page number on a consent form, an impromptu follow-up question inserted into an IRB-approved questionnaire sequence, an extra subject recruited for a study—has the potential to render the entire institution noncompliant.[51] Not only is IRB structure monolithic; the IRB, because of its implicit claim as the arbiter of university research ethics, faces few challenges. The pressures the IRB faces to ramp up its bureaucracy and rules may displace not only its own stated goal of promoting ethics, but also the university's goal of advancing research. Ultimately, in trying to create the appearance of following its own IRB rules to avoid catastrophic lawsuits or loss of federal funding, a university may displace both goals.

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[48] ROBERT K. MERTON, SOCIAL THEORY AND SOCIAL STRUCTURE: TOWARD THE CODIFICATION OF THEORY AND RESEARCH 200 (1957).

[49] Richard A. Hilbert, *Bureaucracy as Belief, Rationalization as Repair: Max Weber in a Post-Functionalist Age*, 5 SOC. THEORY 70, 81 (1987).

[50] EUGENE BARDACH & ROBERT A. KAGAN, GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS 93–119 (1982).

[51] There are inevitably shades of gray in interpretation, but any single act of deviation is supposed to result in redressive steps. If these steps are not taken, the institution has essentially failed in its obligations, rendering it noncompliant as a whole.

III. COMPLIANCE: LOGIC AND PRAGMATICS

The responsibilities that a research institution accepts for carrying out the regulatory promises it makes to OHRP constitute a promise of compliance[52] by which it will regulate its projects, in conformity to OHRP's rules and policies. Weber saw voluntary compliance as basic to "genuine" domination, in that it inculcated, "an *interest* (based on ulterior motives or genuine acceptance) in obedience."[53] Without the organization's members buying into its goals, meeting these goals would entail great cost.

The logic of compliance in the IRB context generates two major problems. First, it creates conflict between university administrators and faculty, who see the selective applicability of IRB review as arbitrary and potentially perverse. Second, because it is uncertain what level of ethical violations will trigger institutional liability, it leads universities to take an aggressively pre-emptive approach to compliance.

A. To Be or Not to Be a Researcher

Among the academic domains that are subject to review by the IRB, what paradoxes emerge when the Code of Federal Regulations Governing the Protection of Human Subjects in Research is put into practice? The first thing to note is that the regulatory steps it prescribes constitute a sequence. When an IRB sets about its task, it first asks whether the work before it constitutes "research" under the federal regulatory definition: a systematic investigation intended to produce generalizable knowledge.[54] What, exactly, systematicity and generalizability might consist of is highly underspecified, though one OHRP statement has described the methods and purpose of the field of history as a negative example.[55] In any case, only when the IRB determines that the work under consideration fits into its regulatory purview does it proceed to determine what level of risk the research carries and thus how the proposed conduct of this research must be evaluated. This sequence of evaluation has several critical implications. (1) The ethics surrounding a project involving human subjects and the risks

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[52] 45 C.F.R. § 46 (2005). Institutions that have not pledged in their FWA contracts to apply federal IRB rules to all their projects are not legally bound to do this, but since most continue to apply these rules to all projects, we will speak, for simplicity, of IRB rules as a uniform system, at least within institutions.

[53] MAX WEBER, ECONOMY AND SOCIETY: AN OUTLINE OF INTERPRETIVE SOCIOLOGY 212 (Ephraim Fischoff et al. trans., Bedminster Press 1968) (1925).

[54] 45 C.F.R. § 46.102(d) (2005).

[55] Oral History Ass'n, Oral History Excluded from IRB Review, http://omega.dickinson.edu/organizations/oha/org_irb.html (last visited Nov. 9, 2006) ("While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences they do not reach for generalizable principles of historical or social development, nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future.")

it may carry for subjects is not the primary determinant of whether a proposed study must be approved by an IRB; rather, the primary determinant is whether the project is deemed to be research under the definition established by federal regulations. (2) The ethical standards that govern the conduct of a project are not necessarily derived from any inherent risks the project may produce but from the definition of that project as research or not, for federal purposes. (3) Not all the projects in a university need be evaluated by the same ethical standards for the treatment of subjects. Though the university's working assumption must be that there will be commensurability across domains, faculty whose projects constitute "research" within the federal definition may be obliged to meet procedural standards that are more onerous than those faced by faculty in other domains, however generalizing or systematic they claim to be. Finally, and perhaps most important, (4) those who engage in what the university defines as IRB-relevant research are more vulnerable than those who do not, because of the scores of extra rules they must pledge to follow to conduct their research. To the extent that researchers have trouble adhering to these rules because of their disciplinary philosophies, they are even more exposed.

Consider how perverse these implications of the regulatory logic must appear from the point of view of faculty investigators. The IRB, seeing itself as the ethical oversight authority for one specific domain of university activity, begins by asking what it must regulate, to which the answer is "research." Faculty, however, assume that anyone a university hires into a faculty position engages in research, though the forms of generalized knowledge that practitioners of particular disciplines produce as well as the methodologies and styles of systematicity they employ vary widely. For many years, the definition of research as a matter of congressional intent drew little interest from nonmedical researchers, a fact that we note by the virtual absence of interest of citations on this matter during the pre-2000 era. But as IRB buildups began to inflate the demands on faculty, these two entirely different assumptions about the purpose of the same organization began to lead, we believe, to some significant sources of conflict between IRB administrators, on the one hand, and, on the other, faculty who try to pursue the safest possible procedures to conduct their research—sometimes in spite of IRB regulations rather than because of them. These faculty watch colleagues and students who do not have to run the IRB gauntlet write their grants and publish their research, using the same methods and with possibly greater risks to their subjects. When the IRB inflates its requirements to the level of impossibility in the domain it has been assigned to regulate—and occasionally suggests to faculty in some disciplines that they do not need to enter the regulatory morass because they do not do research—faculty and students trapped in the IRB catch-22 dilemma of productivity *or* compliance react with dismay. This schism reinforces their perceptions that they have become the scapegoats of a hypocritical anomaly

whose mission is that of protecting the university. It has also led to situations of high irony. Some faculty who advertise themselves on the job market and to their deans specifically on the basis of their excellent research have found themselves casting for rationales that will establish decisively that they do not, in fact, do research.[56]

B. Responsibility for Compliance Failings

If the logic of which academic activity is subject to IRB review can be unclear, it is equally unclear who should be held responsible for an investigator's failure to comply with IRB policy. In cases of breach, the investigator must file a protocol violation with the IRB, a document that describes the specific nature of the violation and steps that will be taken to redress the violation and to avoid future problems.[57] But it is still unclear who is ultimately at fault for these violations. Is it just the investigator? Is the university, that is, responsible only for putting in place an appropriate system of review? Or is the university also at fault for specific violations, whether because of negligent supervision or simply because it is responsible for the actions of its employees or researchers?

A disease metaphor highlights the compliance dilemma. As long as the institution had a sufficient rule structure in place that banned an act in question, this might "immunize" the institution from blame if one of its members did not follow IRB rules. The fault would thus be that of the investigator who could be "quarantined," and corrective steps could be confined to the investigator alone. An "infection" interpretation, by contrast, would see the investigator's violation, however innocent, as rendering the entire institution at fault. Charges of failure by universities to follow their own procedures in supervising their agents have been the grounds for the major cases of institutional closure for noncompliance. Alleged shortcomings in the national cases that have come to light have been significant: protocols being reviewed at a lower level of risk than OHRP standards, failure to submit complete annual reports, and approval of inadequate consent forms, among other things.[58]

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[56] *See, e.g.*, *id.*; Linda Shopes & Donald Ritchie, *Exclusion of Oral History from IRB Reviews: An Update*, PERSPECTIVES NEWSLETTER OF THE AMERICAN HISTORICAL ASSOCIATION, Mar. 2004, at 9.

[57] INSTITUTIONAL REVIEW BOARD, NORTHWESTERN UNIVERSITY, GUIDELINES ON PROTOCOL DEVIATIONS/VIOLATIONS 2 (2002), *available at* http://www.research.northwestern.edu/research/OPRS/irb/forms/docs/ProtocolViolationGuidelines.doc.

[58] *See, e.g.*, Letter from Patrick J. McNeilly & Michael Carome, Department of Health & Human Services, to Edward D. Miller, Chi Van Dang & Gregory F. Schaffer, Johns Hopkins University (July 19, 2001), *available at* http://www.hhs.gov/ohrp/detrm_letrs/jul01a.pdf (letter from OHRP after death of research subject at John Hopkins); *see also, e.g.*, ALLIANCE FOR HUMAN RESEARCH PROTECTION, NATIONAL BIOETHICS ADVISORY COMMITTEE (NBAC) FINAL REPORT (2001), *available at* http://www.ahrp.org/ethical/compliance.php (providing list of citations to other compliance determination letters sent to various universities for possible violations).

There are two important points here. First, despite thousands of pages of official regulations, guidance, commentary, and training materials, there appears to be no consensus in the IRB community on even so simple a question as the scope of institutional liability. Second, this ambiguity surrounding the basis of liability has prompted universities to take an aggressively pre-emptive approach to compliance.

In our experience, many thoughtful IRB administrators readily admit to being unclear on the nature and scope of compliance; as in much of life, the lines are inevitably gray. But the inescapable fact they all must confront is that in those calamitous cases in which it has cut off funding, OHRP has treated the institution as a whole. In the situations of moral panic that these cases have produced, it has been nearly impossible for the most confident of managers to ensure that the decisions they make, which may have institutional repercussions for years, do not bend to the capricious political winds. Given the enormous risks that being branded noncompliant entails, local IRBs' rush to pre-empt federal action is an understandable response. However, these complicated sequences of conjectures on the basis of unknowns and conditionalities—anticipation of possible drastic federal reactions to benign acts of possible noncompliance—have created an IRB culture of pre-emption among U.S. universities: one that seeks to control the course of research to prevent possible offenses.

IV. LOCAL INSTITUTIONAL IMPACTS

If anecdotal accounts can be trusted, then, for most universities, the consequences of the national IRB expansion were overwhelmingly negative. University IRB offices, terrified at the specter of their institutions losing all federal funds, opted overwhelmingly for conservatism. Taking on the unspoken role of protecting the institution from both lawsuits and the suspension of federal funding, they proceeded to develop a number of related responses that the iron cage model might predict. They began to convert choice to requirement, treating the guidelines as rules, extending federal regulations to all non-federal research. They came to define their most fundamental task not as that of anticipating risk to the subject, the original object, but to the institution from noncompliance, no matter how trivial. Hastening to demonstrate compliance and ramp up their rules so they would not be caught on the fence, they trained their staff to catch hints of shifts in the regulatory winds and to share ideas for new measures that might head off federal disapproval.[59]

A brief history of the IRB operation at Northwestern University, the home institution for the majority of the authors, offers a case of how local offices have tried to grapple with the federal changes and of the conse-

[59] *See, e.g.*, Erich Jensen & Judy Nowack, Warning! Warning! Warning! Letters: Rules for the Clinical Research Game (Nov. 17, 2003), *available at* http://www.wlap.org/wl-browser/browser.php?ID=20031117-annarbor-01-jensen.

quences for researchers who were subjected to the expanding IRB bureaucracy. We consider changes in the overall operation of Northwestern's IRB and then turn to an ethnographic description of daily life in the office. We then turn to the experience of our social science panel, a subunit of the IRB. Throughout both subsections, we draw on our own varied experience as participants in Northwestern's IRB system.

A. The Life History of a University IRB Office

Before the 1990s expansion of IRB administration, Northwestern's professional IRB staff consisted of two full-time people. Research submitted from social scientists was reviewed but was usually exempted. Investigators supervising large projects that employed similar methods could sometimes have new projects approved under a general umbrella without having to submit each individual project for IRB approval. In many cases, the IRB did not review pilot projects or student research at all.

The effects of the changes on the workload for both staff and investigators that were wrought by the federal government, together with changes in local Northwestern policy that sought to pre-empt federal scrutiny, were inevitable. Like nearly all other U.S. universities,[60] Northwestern responded to the 1990s changes by ratcheting up the size and formality of operation of its IRB office. The university's Office for the Protection of Research Subjects spiraled from two professionals to what is now a staff of 26, of whom 21 support the IRB operation. Review panels went from one to six—four were created simultaneously in September 2000, with one for the social sciences created a year later, and another medical panel added subsequently—and appointing their membership became the duty of the university's vice president for research. The length of the basic protocol template for new projects went from two pages to its present length of twelve for the social sciences, and fifteen for biomedical research. In addition, the number of supplementary forms and documents required for each submission went from one or two to far more than that, depending on the nature of the study.[61] Many protocols are now better measured in inches of thickness than in number of pages. The level of bureaucratic redundancy, inconvenience and aggravation increased dramatically: Unreturned phone calls, dropped correspondence, and administrative errors on forms became routine. The IRB, because it occasionally lost protocols, began to recommend to all faculty and students, including those in the Evanston-based social sciences, twelve miles north of the Chicago-based IRB office, that protocols be delivered in person to the IRB office. The most palpable change for investigators and staff alike was that of delay: sharp increases in the time required to get studies approved from the time of submission. The time

[60] For a general history of human subjects review in the U.S., see Stark, *supra* note 16, at 169–254.

[61] *See* Institutional Review Board, Northwestern University, Forms, http://www.research.northwestern.edu/research/oprs/irb/forms/ (last visited Dec. 3, 2006).

required to pass review increased from usually around forty-eight hours for social science reviews to what could be months for even the most routine projects. Equally problematic have been the time demands required to grapple with the proliferation of new forms and the obscure and tangential questions in IRB protocols. Most notable is the fact that in the immediate aftermath of the major national and university changes, exemptions were almost nonexistent, and nearly all Northwestern social science projects became subject to full board review. The fact that the panel's convened meetings only occur once a month meant that harmless studies sometimes had to wait months between cycles of revision.

Not just the size of the operation but the scope and volume of the Northwestern IRB's responsibilities exploded. Daily staff routine now centers on the movement of projects through submission and review, and on approval of a legal document that meets both federal and university regulations standards. Staff must ensure that project submissions are complete, secure editorial and substantive revisions to project materials, justify or clarify procedures to panel members and faculty, document permission to conduct research at outside sites, and certify the completion of university-required research training. Other tasks include data entry and filing, conducting training sessions for researchers, responding to telephone inquiries, preparing correspondence related to issues identified by the Board, reviewing responses to determine if issues have been correctly addressed, and managing the enormous volume of e-mail correspondence. Convened or "full" panel meetings require additional logistical tending: project assignments and distribution, arranging meeting space, and sorting and processing of project materials after the meeting. At these meetings, IRB staff provide information for the committee and draft minutes which, along with other documents, become institutional records. Some staff members also receive assignments for specific projects such as the implementation of new submission procedures, preparing responses to audit agencies such as Department of Health and Human Services or the Food and Drug Administration, or remedying compliance errors highlighted in those audits. Others revise existing questions and forms in an attempt to make them more user-friendly, or as new cases bring policy ambiguities to light. In all this, staff members and administrators must attempt the often-impossible task of satisfying investigators, boards, and its own readings of the federal requirements.

Recent Northwestern IRB administrators, trying to counteract the problems that the expansion of IRB activities has generated, have tried to move toward the service side of the service–compliance continuum that all IRBs must straddle. The mandate from the Northwestern IRB office to treat nearly all projects, regardless of their risk level, as requiring full board review has been sharply reversed, in both the medical and the social sciences, and a more careful reading just last year of the federal language of exemption has allowed us to move many projects back into exemption. At pre-

sent, only a tiny minority of submitted social science projects are required to undergo full review. Some research has gone through approval more quickly due to a decline in protocols describing new research, and a concomitant increase in the number of revised applications submitted. Staff and committee members make themselves available to help students and faculty understand the application requirements and templates, to interpret the outcomes of panel review, and to draft responses to questions their protocols raise in review. They try to be courteous to frustrated faculty and students, sometimes staying after hours to instruct a class or to offer guidance, even to undergraduates. Most recently, our IRB launched eIRB, an electronic submission platform, to facilitate its own record keeping and to speed the process for investigators. First reports suggest that the changes are making a significant difference in the burdens associated with an IRB submission, though they also have the potential to lead researchers to treat the ethical dilemmas that research can genuinely raise as a cut-and-paste affair. Despite improvement in efficiency and service, the preparation of protocols still consumes enormous amounts of faculty and student time, especially for new projects the IRB considers to carry greater than "daily-life" risk, or for protocols that depart from conventional procedures or deal with populations IRB considers vulnerable.

B. The Social Sciences Panel

At the level of "Panel E," the Northwestern IRB panel specific to the social sciences, the cascade of federal regulatory demands has hit hard. For their personal energy and professional service, social science panel members face a mixture of gratitude and vilification. Most faculty are grateful for the help that panel members render for helping them through the IRB quagmire. And when they express resentment of the process and the damage to their research and the waste of time they experience, most faculty are careful to preface their critiques with, "We know it's not your fault," or "We know it's just the bureaucracy." Nonetheless, it is hard for panel members not to feel that they are the targets of invective and blame that surround an IRB. The composition of the panel has been a telling sign of the regulatory strain. At first faculty from a broad university constituency willingly participated in the panel's reviews. Growing resentment of the IRB process as well as skepticism of its agenda, however, has changed this. As we have heard from numerous colleagues who were approached to serve on the panel, the cost of such tremendous personal and professional energies required to review increasingly complex protocols, combined with the need to face frustrated students and faculty, has made many faculty members reluctant to serve.

The review process itself brought the most challenges for panel members themselves. Besides being a moving target, IRB review has proven to be a particularly ill-defined one. In the experience of those of us serving on IRB panels or as IRB administrators, we have been struck by how reviewers

must interpolate between significant variation in the cases they see and what, at first glance, seems like an avalanche of rules but which in practice boils down to a paradoxically small number of vague and wrong-headed regulations. What sometimes results to fill in the spaces is a sort of case law that is not written down except in the form of meeting minutes which, in our experience, are almost never consulted by subsequent reviewers. To the extent that these precedents carry forward, they do so only because they reside in the recollections of a revolving set of actors. Much depends as well on an idiosyncratic chemistry of who is assigned to review a protocol, who is present at the meeting, and how fallible their memories are.

The evolution itself of this case law and other committee-generated practices has a history that is important to highlight. When the ratcheting up of the IRB bureaucracy at Northwestern was occurring, administrators were working in an environment in which suspension of federal funding to other institutions had produced considerable anxiety. It was no secret that the Northwestern IRB director was under pressure to bring the university into full compliance as quickly as possible. In a situation in which projects were routinely delayed for months or even abandoned entirely, social science panel members, who understood well the potential consequences for careers of making the smallest mistake in a protocol submission, spent a great deal of time trying to pose solutions to IRB administration. In that climate, however, the panel's suggestions often met with the response that the OHRP would not approve. For several years, no one had a firm basis upon which to counter the alleged federal position. Indeed, OHRP intent was likely not transparent even to the agency itself. IRB panel members, who were less expert than administrators, had no choice but to accept what they were told by administrators. Very much as the national and local IRB administrations appeared to be doing, however, Northwestern's social science panel began to use the case law model, trying to use prior decisions that our administration had approved as workable precedents for subsequent cases. It also tried to draft templates for consent forms, and to provide examples of hypothetical instances that would point investigators to what it hoped might be safe pathways of wording, some of which have since become permanent fixtures of Northwestern social science templates. Often the wordsmithing solutions helped. Once these wordings were accepted in the general IRB culture, however, our reviewers came to expect them, sitting up to take critical notice of variations that may well have posed more thoughtful solutions of particular cases.

As this description suggests, even a separate social science IRB enterprise suffers from internal tensions between the need for standardization, whether imposed by OHRP rules or by our own desires to ensure equity, and the need to allow the very stuff of novelty that studies are supposed to produce. We have observed that social scientists who confront their review assignments can be no less critical of their fellows' studies than a biomedical panel might be. Indeed, IRB staff have sometimes had to step in diplo-

matically to rescue a project from a zealous social science faculty panelist threatening to dismember it altogether. In this regard, we have observed a typical life cycle for social science panel members. The typical panel member begins his or her tenure by making it known that a great deal of harmless social science research is delayed without any reasonable cause, and that henceforth the reckless invasiveness of the IRB must be tempered. Yet this same panel member, when given projects to review, is often the most critical.

This pattern reflects a broader impulse among social scientists. We think of ourselves first and foremost as academics. Our business is to read research proposals, journal articles, student papers, and to find fault. Turning to IRB protocols, we become fastidious reviewers. When we read consent forms, it is hard for us to refrain from editing them. When we read with an eye toward possible risk, whether large or small, our expertise itself will unmask it. As social science panel members, we will inevitably find problems with social science IRB submissions; we cannot help ourselves. Importing our own disciplines' ethical dilemmas, the concerns that we raise often go far beyond those imagined by the federal legislators. They also hand the IRB, seeing our plight, both our fears and our language of expressing them to incorporate into its already overburdened repertoire. Over time, such impulses are tempered, and we learn to see the big picture again. In the meantime, however, the damage to the research enterprise is done.

In retrospect, giving the social sciences a separate review channel and letting them into the review process was helpful in that the social sciences gained mediators who could explain studies to their panel colleagues and attempt to buffer the power of the medical model. At the same time, our social science panel's own efforts to help both added to the layers of regulatory stratigraphy and intensified the regulatory flux. All this has undoubtedly provided further grounds for investigators to conclude that the IRB was capricious and inconsistent.

V. IMPACT ON RESEARCH, AND PARTICIPANTS' RESPONSES

In the preceding sections, we laid out a framework for thinking about the regulation of creativity. In addition, we described the recent history of Northwestern's IRB, placing particular emphasis on the impact of the national ramp-up on the local IRB review of social science research. In this section, we turn to the impact of these larger institutional changes on investigators and the research they conduct. In doing so, we return to the two key questions posed by this article: (1) How, in the face of this tightening regulatory vise, has research, and particularly social science research, survived at all? And (2) how might it have changed in order to do so?

To document the experience of investigators, we can, in part, rely on our own experience, since we are investigators as well as IRB panel members and former staff. However, in addition to drawing on our own experi-

ence, we also wanted to draw on the experiences of our colleagues. On this we already knew quite a bit, since their IRB experiences are much of what those of us who have served on the panel hear anyway from them. In order to collect some of those experiences in writing, we sent an e-mail to three social science departments, with several open-ended questions, asking them to write back with their experiences. One of these departments specializes in laboratory experiments; the other two are highly field oriented. We asked them to describe the most challenging aspects of the IRB system, their tendencies to avoid or alter areas of research or teaching because of IRB, and changes they may have observed in the IRB system over the past few years. Twenty- seven of our colleagues wrote back to us. Although the responses were modest in number, our sense is that they fairly represented the views of individuals in these departments who have had the most frequent dealings with IRB. In the discussions that follow, we draw on their answers, in order to illustrate and give some more substance to our points.

A. IRB Impact on Researchers and Research Substance

For IRB-affected Northwestern social science students and faculty, the intensified OHRP efforts to regulate their academic conduct and products were disastrous, imposing unnecessary hindrances to academic teaching and research. However, the specific effects have been complex, presenting researchers with a number of options. At one extreme, researchers might ignore the IRB and carry on with their productivity; at another, they could conform all of their research and teaching conduct to the letter of IRB requirements. There is also a broad range of what Kjeldgaard has elegantly termed "principled dodging."[62] We focus on two principal gestalts generated by the struggles over regulating creativity. One response we call a deterrence impact, leading to the quashing of academic research and teaching products. The other we call "consensual censorship," a phenomenon that we believe has not only allowed IRB-relevant research to proceed but has become an odd source of new efforts to lay down cautious pathways to make research possible, albeit in constrained ways.

1. Deterrence.—In this category, deterrence, we describe patterns in which some facet of research or teaching that, while not expressly forbidden by the IRB, researchers have avoided to side-step IRB hurdles or have modified in ways designed to lower the costs of IRB compliance. The impacts can be variously described as "chilling," in the sense of discouraging research, and "distorting," in the sense of gratuitously altering it and possibly undermining its academic value.

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[62] Erik Kjeldgaard, *Anthropology and IRBs: A Response to James Boster*, ANTHROPOLOGY NEWS, Sept. 2006, at 5 (2006).

a. Research.—The deterrence effect on research occurs not because the IRB expressly forbids certain projects, but because IRB demands would so delay or distort them as to render them not worth doing. Rather than confront the scale of regulations that would delay approval, a researcher may "dumb down" a research project, remove pieces of it, or even abandon it altogether. IRB pre-emptive barriers were reported to not only delay and discourage research, but also to distort its substance. To be sure, changing cultures of research practice that can pose unnecessary risks to subjects is the IRB goal. As a number of our colleagues have emphasized, however, both in person and in their responses to our email query, they alter their course not because of any real risk they perceive to their subjects but simply to pass IRB muster. Trying to reduce their own professional risk, they divert their work, choosing topics or populations selectively, or adapting methods that will entail less demanding IRB review and lessen the probability that they will have to make substantial changes before proceeding. IRB procedures, that is, can snuff out ambition even before the project begins.

The disturbing point is that it is the mere anticipation of onerous IRB review that can result in some alteration of the proposed protocol. Because of the potential for delays and the IRB tendency to intrude into each step of the research process, many social science faculty report that they think twice about taking on research topics, methods, and populations that IRB frames in the mode of risk. One respondent described the impact thus:

> The IRB has become a nightmare over the years that I have been a researcher. I'm sure most of this pressure is coming from the federal government, but the rigidity of the model (based on the medical sciences) and the number of hurdles/forms, and the scrutiny (to the point of turning back projects for mispagination or other pithy errors, as has happened for some of my students) is just terrible. It is very discouraging, and I find myself thinking of EVERY new research project as it relates to the possibility of IRB approval.

Two respondents indicated that faculty had moved toward non-field projects in large part because of IRB. One faculty member even pointed specifically to concerns about IRB in a decision to make a career shift away from field-project themes and methods that might jeopardize the researcher's career:

> Since last year, my research became more theoretical in large part because of IRB requirements. I simply try not to do any research which would involve Panel E [the social science review panel at Northwestern]. . . . I no longer interview people during my trips abroad and try to limit the data gathering to passive observation or newspaper clippings.

The sense in the responses that IRB could delay, sidetrack, or even stop research was marked. Causes of delay are difficult to assign definitively. When a study is sent back to an investigator with an extensive list of panel concerns to address, the investigator in some cases has taken weeks or

months to respond; some did not respond at all, choosing, we suspect, to withdraw the project. With IRB demands spiraling, however, projects such as faculty summer research or student research projects with sharp time constraints were hard hit. International trips had to be cancelled, undergraduate projects were abandoned, and at least one tenure clock had to be set back because of IRB delays. One respondent in our faculty query declared, "It used to be (say before 1997) fairly easy to get a proposal through IRB. Now it is easier to write the grant proposal than an IRB proposal." Others implied that they had become resigned to a lengthy IRB ordeal for new studies as a way of life.

The most obvious example of a research domain for which the complexity of requirements appears to have acted as a deterrent is that involving children. Following federal requirements, Northwestern's standards require separate consent procedures for parents and children, with the form and content highly specified by the age group of the child. While legal minors cannot sign "consent" forms, verbal "assent scripts" must be approved for children aged 5 to 9, and, for children aged 10 to 17, written "assent" is required.[63] Intimidated for several years by these demands, almost no one outside the fields of education, psychology, and linguistics studied children. Within these fields, such studies were usually conducted in domains that were easiest to frame in highly controlled terms, such as within the confines of a lab or a school. Other studies have side-stepped heavy IRB demands by focusing on "former children," adults who reflect retrospectively on their experiences as children, despite all the loss of richness and reporting accuracy this strategy entails. In 2005, Northwestern cautiously began to broaden the scope for designating studies of children exempt, and the number of observational studies of children may be inching up again.[64] The condition for conducting such studies, however, remains that researchers vow not to engage in the activity they are observing with their child subjects, even if approached by a child.[65] A student engaged in an exempt observational study of children who actually joins their game of tag is still required to fill out the same protocol violation form, heavily laced with medical and legal terms, and phrased in the language of rebuke, as a researcher who accidentally doubles a patient's radiation dosage in a medical trial.

IRB is said to pit the research worlds of the hard and soft sciences against each other, with medical and laboratory researchers finding the

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[63] *See* OFFICE FOR PROTECTION FROM RESEARCH RISKS, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, PROTECTING HUMAN RESEARCH SUBJECTS: THE INSTITUTIONAL REVIEW BOARD GUIDEBOOK 6-18 to -25 (1993).

[64] This trend was pointed out in personal discussions with Andrew Ellis, an IRB Manager in the Office for the Protection of Research Subjects at Northwestern University.

[65] 45 C.F.R. § 46.101(h)(i), at n.1 (2005); *see also* Exemption Guidelines for 45 C.F.R. 46, http://www.research.northwestern.edu/research/OPRS/irb/forms/docs/NPSFExemptionGuidelines.doc (last visited Nov. 11, 2006).

model more commodious than do those who work in more naturalistic domains. Indeed, the few faculty in our email communications who reported no problems or minimal ones in the requirements that IRB imposed tended to be members of the lab-oriented department. But being chained to a deductive model can affect researchers who work primarily in "hard" sciences no less than those whose work lies in the "soft" disciplines. Every researcher relies on serendipities to open up the idea horizon as well as to control its parameters to affirm and sharpen as well as to explore variations that might prove the rule. Ideas can be gleaned no less from a clinical encounter with a patient for whom an "off-label" medicine was prescribed (no IRB oversight required, as long as the intent was the "practice of medicine"[66]) as from a qualitative interview. Thus, faculty in the laboratory-oriented department who reported that they conduct field studies voiced responses similar to those of researchers in the field-oriented disciplines whom we queried. Some of the most interesting responses of all, coming from those whose studies have been consistently laboratory-based, voiced concerns that IRB pressures had led them not only to alter their research by changing recruitment strategies and avoiding certain populations, but also by employing what they perceived to be undesirably rigid methodologies. The comments of two faculty members pointed to the frustration that the laboratory model creates among even laboratory-based researchers:

> My colleagues and I changed our method of recruitment for one study, because the permissions the IRB was asking us to get were not realistic. I have had to codify the methodology of one study much more than I would have liked (I would have preferred it to remain much more open-ended, in response to findings from the field). And I seriously considered not doing one series of studies because of the IRB hurdle. In general, the main "alteration" is delay and hassle, and the difficulty of doing inductive research [in which] the methods of investigation are modified on an ongoing basis, as determined by the empirical findings.

> If somebody gets a brilliant idea that will result in a tiny protocol change, 3 months may be wasted before it can be tried. I am often tempted to just do what is needed and get the permission whenever.

One possibility that these responses suggest is that the filters that IRB uses to review the laboratory sciences have led researchers in these fields to take for granted the review demands they now experience. This may offer them less freedom to imagine what the pursuit of knowledge in their field might otherwise consist of, even if their disciplinary practices gave them the scope to do so.

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[66] Information Sheet from the Food and Drug Administration Regarding the Use of "Off Label" Drugs, http://www.fda.gov/oc/ohrt/irbs/offlabel.html (last visited Feb. 1, 2007).

b. Teaching.—Besides the impact of IRB on suppressing research, responses to our faculty email describe a substantial toll on teaching. Because each new IRB-relevant project proposed by a student entails significant costs in faculty time and substantial faculty risk, our sense from colleagues is that the IRB system has had a particularly stifling effect on student research. A number of respondents indicated that they had discouraged students from pursuing original research because they feared a delay in approval would not allow the students to complete a project or because the faculty member did not have time to help the students write the protocols that could pass IRB muster. Several individuals gave concrete instances of the "teaching effect" of IRB for their students. Two examples:

> [IRB regulations] put restrictions on the kinds of mini-research projects I create for some of my undergraduate classes. In some classes I have insisted on the collection of secondary sources only, that is, not first hand observations.

> [IRB regulations] have a direct effect on what I advise students to do for their senior theses. I discourage original research that involves primary data collection, and instead steer students toward in-house sets of previously collected data.

Pointing out that the easiest way to ensure that students engage in original data collection and analysis is to say the activity is for coursework only and will not be disseminated—hence, that it is not IRB-defined research—a number of faculty said they discouraged student research. The result in some instances was that the students could not use the results of their work for publication or for national prize competitions or even to send to graduate admissions committees. (Related one faculty response to us, "A student apparently gave up after I warned her of IRB.") Reports of depressing effects on teaching come especially from the field-oriented disciplines. Many of these respondents report that they discourage students from undertaking field projects, or that they steer students away from research projects involving topics or populations that the IRB considers "touchy." Besides edging students toward library projects or toward secondary data sets that will require minimal or no IRB submission, some social science faculty reported that they hesitate to allow students to tackle issues of major social import such as abortion and crime, or have them collect data from populations that IRB defines as vulnerable,[67] such as immigrants and children:

> I discourage students from studying any group that might be construed as a "special population." That means school observations or youth group observations are automatically out. But I have come to learn that the IRB also raises its eyebrow at more nebulous categories, such as gays and lesbians, or poor workers. It basically makes me worried about [studying] any population that is not adult, well-adjusted, crime-free, middle class, heterosexual, white (i.e.,

[67] 45 C.F.R. § 46.111(b) (2005).

> do not study immigrants as some of them might be undocumented or do not study black workers because some of them may fear reprisal from their white employers), and male (i.e., women might report domestic violence). This is, of course, an exaggeration, but the layers of fear that IRB creates leads to this kind of [faculty] policing of student projects.

Undergraduate research projects, which university recruitment materials and undergraduate officials now press very hard at Northwestern,[68] may suffer the most casualties of the IRB system. Their careers are at less immediate risk, if there is no original research project, than are those of graduate students. In the cases of lab disciplines, faculty can often subsume an undergraduate under a project of their own. With more undergraduates to supervise than graduate students, however, disinvesting from undergraduate research may be the most expedient course. As one long-time professional in the field of university administration reflected to us, a four-year college, with its tangential OHRP research relevance, may be a better choice than a university for students with ambitions to engage in research. Finally, we note that in many cases faculty do not actively try to deter students from research. Instead, students deter themselves. Students may come to their advisors with ideas already formed about the IRB boundaries of what they can and cannot do. These faculty mentors, mentally weighing risks of time and effort posed by a new project submission, may have to say nothing at all.

In this brief survey of the deterrence effects of the IRB on research and teaching, several clear patterns emerge. Many investigators, anticipating the IRB obstacles they face, decide on a course of research action on the basis of IRB categories of risk and review. If the study involves their own research, they are likely to proceed, sometimes placing limits on its scope. If the study involves student research, especially that of undergraduates, they are very likely to divert it to non-IRB areas or into areas that will require light levels of IRB review. To the degree that the perceived risk of onerous IRB review increases and, with it, anticipations of the distortions the project would have to undergo to pass—in short, to the extent that the IRB iron cage threatens to "displace" the goal of research—investigator reluctance to undertake such research increases.

2. Consensual Censorship.—Given these regulatory incursions into their academic productivity, it should not be surprising that many researchers dread the IRB process, resent its effect on chilling and distorting their research as they attempt to avoid onerous IRB regulation, and look with

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[68] *See, e.g.*, Office of Fellowships, Northwestern University, Research Opportunities for Undergraduates at Northwestern University, http://www.northwestern.edu/undergrad-research/require.html (last visited Nov. 11, 2006); Office of the Provost, Northwestern University, Undergraduate Research Symposium at Northwestern University, http://www.northwestern.edu/provost/students/research_symposium/ (last visited Nov. 11, 2006); School of Education and Social Policy, Northwestern University, Research Opportunities, http://www.sesp.northwestern.edu/ugrad/community/announce/opportunities/ (last visited Nov. 11, 2006).

envy to others whose topics and methods allow them to avoid IRB review. A "deterrence" model of consensual censorship, however, goes only part way toward explaining how the research enterprise persists within the iron IRB cage. Grants continue to be obtained, articles continue to be published, and talks continue to be given in domains that involve research on human subjects. In short, neither a pure deterrence effect nor a straightforward model of censorship quashes research in the way that we might expect IRB obstacles to do. To capture the more elusive ways in which researchers confront IRB barriers, we turn to forms of what we call consensual censorship: forms of collusion that appear to blunt the force of censorship in its barest forms. By this we refer to the mutual agreement, implicit or explicit, between regulators and those they regulate to refrain from certain expressions as well as the activities that generate the knowledge on which such expression is built.

Consensual censorship, we believe, provides a more robust explanation of how research survives. Arising from the interstices of the IRB regulatory institution itself as its participants collectively face the regulatory ordeal, it emphasizes participants' joint efforts to try to move research forward not, perhaps, to the extent that the investigator might do absent the constraints of IRB review, but in ways that soften the regulatory scrutiny the research must undergo. This response to IRB obstacles, though more diffuse and harder to describe than the relatively straightforward deterrence model, is of course far more interesting. Key to this model are the dynamics of informal networks.

Censorship can be enacted by brute force. But indirect censorship is equally effective in suppressing expression. Theorists such as Althusser (describing "ideology"),[69] Parsons (the "socialized actor"),[70] and Foucault ("governmentality")[71] have shown that society imbues its members with implicit notions of limits on action, inculcating them with the incentive to comply, and effectively assisting power holders to rule them. To the extent that members internalize these norms and act in accordance with them, they relieve authorities of the need to use force. Inspired by the Weberian legacy, however, but also seeking to deepen its insight, has been a powerful strain of sociological work on the less-obvious informal networks and alliances that emerge to counteract the dysfunction created by an institution's demands for compliance. Such analysts see organizations as entities with lives of their own, replete with informal mechanisms, communication networks, status systems, and shifting coalitions of members with their own alliances with the external world and pacts with those higher up in the

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[69] Louis Althusser, *Ideology and Ideological State Apparatuses: Notes Toward an Investigation*, *in* MAPPING IDEOLOGY 127 (Slavoj Zizek ed., 1969).

[70] TALCOTT PARSONS, THE SOCIAL SYSTEM 207–226 (1964).

[71] Michel Foucault, *The Subject and the Power*, *in* BEYOND STRUCTURALISM AND HERMENEUTICS 208 (Hubert Dreyfus & Paul Rabinow eds., 1982).

organization.[72] All emphasize that an organization's insistence on compliance to stamp out malfeasance, if allowed free rein, would force its members to either defect or devise strategies of deceit in order to survive. What keeps an organization together and its goals on track, in this approach, are less its own formal rules than the personal networks that regulators and regulated establish within and across its formal lines.

In an environment that values service to investigators and tries to facilitate their research, investigators and the IRB must strike up collusions in which participants in a social order construct an unspoken set of understandings through which they can communicate—or obfuscate.[73] To accomplish their common goal of facilitating research, participants tacitly agree to orchestrate their exchange of information in such a way that potential elements of an inevitably gray factual world can be framed using language that may pass IRB muster. IRB representatives try to help investigators by pointing to possible red flags and suggesting ways to negotiate them. In some cases, this may require leaving unspoken aspects of the conduct of research that might be difficult to fit within the IRB's matrix. In others, it may require researchers and IRB representatives to rephrase attributes of the research that might otherwise make IRB approval practically impossible. In all cases, IRB representatives thus ask, and investigators tell, exactly what is required—and nothing more. Like the patterns that emerge in the deterrence model, the collusion model turns IRB logic back on itself. In forms of collusion that produce consensual censorship, however, the regulator and the regulated do something we might least expect: hiding in plain sight, they use the very rigidity of 45 C.F.R § 46 language itself to negotiate workable pathways. In possibly the majority of cases, they shape the text in terms that others in the investigator's discipline would find uninteresting at best.

Such compliance collusions can occur in many settings. At the smallest scale are the one-on-one encounters between panel members or IRB staff with an investigator prior to a formal protocol submission. Sometimes, in fact, the participants know one another only as a class of persons or through departmental scuttlebutt. An investigator's interest in such collusion might be predictable, as might the character of the IRB protocol the collusion produces. Although collusion requires two participating sides, the regulator's perspective presents the more interesting question. We have already described the informal, one-on-one meetings that may occur prior to full review. At the panel or evaluative level, where the collusion continues

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[72] *See, e.g.*, W. RICHARD SCOTT, ORGANIZATIONS: RATIONAL, NATURAL AND OPEN SYSTEMS 31 (2003); PHILIP SELZNICK, TVA AND THE GRASS ROOTS: A STUDY IN THE SOCIOLOGY OF FORMAL ORGANIZATION (1949); Mark Granovetter, *Economic Action and Social Structure: The Problem of Embeddedness*, 91 AM. J. OF SOC. 481, 501–02 (1985).

[73] P.P. McDermott & H. Tylbor, *On the Necessity of Collusion in Conversation*, *in* THE DIALOGIC EMERGENCE OF CULTURE 218, 219 (D. Tedlock and B. Mannheim eds., 1995).

once an investigator submits a finished protocol, the panel tacitly agrees to confine its regulatory gaze to exactly what is brought before it. Focusing on precisely those facets of a research protocol that can easily be committed to paper, the panel refrains from asking much else.

The best example here is the treatment of the consent form. Across institutions, consent forms are subject to intensive review; reviewers quibble over everything from "is-it-eighth-grade-language"—the general working definition of language that is understandable to a subject[74]—to individual words and formatting. Across institutions as well, there is an understanding that the consent process in human-subject research takes place in an ongoing relationship, and that investigators see the long, technicalities of consent forms as introducing an off-putting distance between them and research subjects.[75] Especially when the subjects and investigators know each other personally, as is common in social science research, the investigator must engage in what interactionist sociolinguists call "repair" work[76] during the event. Hastening to shore up a friendship that the high legalisms suddenly throw into question, an investigator may make light orally of the consent form and of the required verbal reiterations of it, or interject into the language of caution and rights implicit reminders of friendship. To diffuse the consent situation, investigator and subject may even create a joking definition of the exercise. Much of the need for this unregulated consent-related discussion between investigators and subjects, in fact, is likely driven by the arcane nature of the consent form itself: the longer and more legalistically distancing the consent form, we suspect, the more the truly meaningful informed consent action may shift to informal messages. But investigators avoid explaining this, and IRB panel review avoids probing for it. Both sides concentrate on the wording to get the written form through review and signed by the subject, leaving it to the investigator to conduct the real consent process in the most civil way possible.

Another manifestation of consensual censorship at the panel level emerges in the fact that IRB review filters shift for different genres. That is, investigators agree tacitly to present their studies within a particular conventional repertoire, and IRB members agree in similarly tacit fashion to inspect them through the specific evaluatory lens that corresponds to that repertoire. At Northwestern, these tacit agreements surrounding communication take concrete form in the boilerplate language the IRB provides for

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[74] 45 C.F.R. § 46.116 (2005).

[75] *See, e.g.*, Bradford H. Gray, *Complexities of Informed Consent*, 437 ANNALS OF THE AM. ACAD. OF POL. & SOC. SCI. 37 (1978) (arguing that there is too much focus on consent forms rather than the collective relationship between doctor and subject); *see also* Rena Lederman, *IRB Consent Form Dilemmas and the Importance of Local Knowledge*, ANTHROPOLOGY NEWS, May 2006, at 21, 22 (describing the difficulty of human rights researchers who are concerned about consent forms falling into the wrong hands and identifying those individuals that assisted with their research).

[76] Emanuel A. Schegloff, Gail Jefferson & Harvey Sacks, *The Preference for Self-Correction in the Organization of Repair in Conversation*, 53 LANGUAGE 361, 361 (1977).

consent forms, the consent form templates, and the sample submissions that IRB itself generates, suggesting a language and set of procedures it is likely to find acceptable. Restricting their communication to the exchange of well-known pathways in a pre-approved set of blocks of text, investigators and IRB representatives agree tacitly to confine the written text from straying into dangerous territory. These devices allow communication to pass through a narrow and thoroughly vetted set of channels of a review genre to try to maximize the chances of IRB approval.

An illustration of how various panel review filters have arisen to accommodate different research genres is provided by the contrast between laboratory research and ethnographic research. Laboratory-based researchers are expected to document exhaustive moment-by-moment plans for the interaction that will take place between investigator and participant. If an interview is to be conducted, every question will be submitted; if some manipulation or test is to be performed, every motion will be described. This detailed interview protocol will be reviewed by an IRB reviewer who may raise issues that relate, in an equally-detailed way, to a close textual reading of it. Research presented using the language of ethnography, on the other hand, shifts the lens to a broader methodological and observational landscape of review expectation. For several years after the IRB ramp-up began, our IRB panel expected detailed interview protocols from everyone. Now, an ethnographer who intends to employ participant observation does not need to provide a detailed specification of what is to be said to participants, and is not asked for it. Without such collusion, ethnographic studies would not survive under the IRB system. As much as social scientists complain about the ill fit their projects pose in IRB review, their own protocols are now spared this level of scrutiny.

Compared to another form of consensual censorship that the IRB and its constituents have developed, however, all we have described above seems petty. Nowhere, in fact, is consensual censorship emblemized more strikingly than in the creation of the social sciences panel itself, when in 2000, Northwestern itself—like many other major university administrations—legitimated a multiple-filter approach by creating a separate panel that split the review process between medical and social science studies.[77] Far less, even, than the other manifestations of consensual censorship, this one no longer needs justifying, whether because the university itself set up the structure or because it occurred so far in the past that it is now taken for granted. It is now the first step in a well-structured commonsensical pathway of service.

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[77] For just two of many other universities' social science IRB committees, see, for example, Human Subjects Review Board at John Hopkins University, http://web.jhu.edu/Homewood-IRB (last visited Feb. 1, 2007) (separate website for review board handling social sciences); Office for the Vice President of Research, University of Minnesota, About the University of Minnesota Institutional Review Board, http://www.research.umn.edu/irb/about/ (last visited Nov. 11, 2006) (website listing different committees dealing with different topics, including social sciences).

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Looking back, we are drawn once again to Weber's compelling image of the iron cage of bureaucratic rationality, which has been the inspiration of countless studies in the sociology and politics of formal organizations. The biggest hole in the vision, however, was its failure to recognize the power of the personal relationships that emerge as members of the bureaucracy try to do their jobs within the limits posed by time, money, and patience. The IRB system may be run by a hierarchically organized cadre of specialists who exercise judgment over the conduct of research and who can stop that research for anything less than airtight compliance with ill-fitting standards. Its faculty panelists may use the forum to demonstrate their academic prowess and they may raise concerns that become unintended weapons of regulation. The system is far from impersonal, however. That any creative research at all has survived under the IRB system, distorted as we believe it has become, must be attributed to the dynamics of consensual censorship between investigators and IRBs.

Investigators adapt to the conditions the IRB imposes with a mixture of acquiescence and informal strategies; the IRB itself refrains from policing and tries to help investigators to find vocabulary and pathways that will avoid problems. All of this may be described as censorship, though no more than it has resulted in wholesale accommodation, neither has it resulted in wholly censored research or teaching. The great majority of investigators carry on—and they do not consider themselves noncompliant. Nor, in most cases, would we. There is no intent to encourage noncompliance or to do anything in the research that is ethically wrong. The collusion that produces consensual censorship is intended simply to find language that will facilitate IRB approval. In some cases, this allows a study to go through unchanged; in others, it results in modifications to the proposed research itself, sometimes in ways that may be warranted by genuine concern for subjects but often in ways that are not. What is so compelling about such cases is the language of ethics and research that social scientists provide to themselves as they try to create margins of safety based on the most conservative guesses about worst-case interpretations of the federal administration. Without developing some language of compliance complicity, the regulatory burden would undoubtedly lead to massive numbers of tenure denials and early retirements for social science faculty who turned in blank sheets on their annual research-activity statements to their deans.

Even more important are the implications for institutionalization of consensual censorship. The one-on-one consultations between panel members and distraught researchers that began in the early days of the freeze took place in an atmosphere of almost furtive back-room deals, characterized by delicate ballets of "don't ask, don't tell." Reflecting on the changes since then, we have realized that most of the elements of what were initially

informal collusions have become taken for granted and effectively institutionalized as part of the IRB service package. In particular, the creation of a special social-science panel within the IRB of Northwestern and other universities has itself provided by far the biggest and most conspicuous stamp of legitimacy for tacit collusion. The fact that consensual censorship is not only coming out of the closet but becoming institutionalized may appear to offer a message of hope, and even to indicate a broader inclination to swing the regulatory pendulum back toward a service ethic. At a minimum, whatever has generated these odd new dynamics of IRB review, the result is hardly the one-size-fits-all approach that IRB opponents sometimes claim it to be.[78] Though there is good reason to despair about the penetration of the IRB system into U.S. universities, what we may be seeing in consensual censorship are signs of the system groping its way forward after the years of freeze-up. Players at all levels are not just seizing on interpretive possibilities in the rules and categories, but, by making them everyday practice, they may in some instances be managing to institutionalize those that work, moving them from arenas of furtive suggestions to out-front, mainstream behavior.

Reflecting on the IRB system as both its victims and its perpetrators, we can point in hindsight to our panel's history in ways that make these dynamics of consensual censorship unsurprising, particularly to informal-organization theorists. However, these responses to regulation have led us to two unsettling conclusions. First, the act of participating in consensual censorship means that we—and indeed faculty and students themselves as they devise pathways to do their work—engage in the same efforts to create wide margins of risk that IRB administrators do. We do so, however, in a way that specifically undermines the reason why we came to the university in the first place: to be creative. Second, while it is easy to blame administrators for the spiraling IRB woes of social sciences, our own actions as academics have unquestionably contributed to the elaboration and institutionalization of the code by which we are regulated. IRB administrators increasingly defer to us as experts who can help to refine the model for the academic sphere that has proven the most awkward fit with the IRB system. The wordsmithing our review panels devise to help students and colleagues survive the IRB ordeal allows social science researchers to get their projects approved and it gives IRB administrators something to show the federal government. But the fact remains that social science concerns, whether contrived for reporting purposes or real, find their way into the repertoire of IRB demands. If these most unlikely bedfellows, social scientists and IRB administrators, have jointly produced many of IRB's more gratuitous requirements, then rather than being an unmitigated blessing, the addition of

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[78] *See, e.g.*, Center for Advanced Study, *Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"* (U. Ill. Law & Econ. Research Paper No. LE06-016, 2005), *available at* http://www.law.uiuc.edu/conferences/whitepaper/summary.html.

social scientists to the IRB process may have increased social scientists' IRB woes as much as it alleviated them.

VI. WHAT KIND OF MODEL?

The IRB must claim to represent ethics. Many would argue that while IRB review is onerous, there are enough recognizable elements of ethics to tolerate its intrusiveness. As its requirements have grown, however, other characterizations of the model appear to have become more salient in the minds of most social science investigators. To understand this impact, we reflect on the kind of cultural model the IRB has come to represent, not in ideology but in practice. Although, as we noted, each university creates its own policy configuration to implement the basic federal regulations, some general observations can be derived. For this discussion of the IRB as a cultural model, we concentrate on the IRB's primary working document, the protocol.

A. Legal

IRB is almost invariably described by its critics as a medical model. Whatever it is metaphorically, however, an approved IRB protocol is first and foremost a legal contract, i.e., an agreement between an investigator and the university that specifies a set of activities, assigns responsibilities for conducting them, and binds the parties to its terms. In its protocol contracts with investigators, the IRB acts as the representative of the federal government, which requires its grantee institutions to be able to monitor the conduct of the activities of all the research projects they sponsor. It also acts as the representative of the university, which adds its own rules as well. The protocol and its related documents include a number of elements: declarations of risk, provisions for oversight and control, petitions for waiver of standard procedures, safeguards of security and privacy, reporting requirements, statements of wrongdoing (as reflected in protocol violations), and so on.[79]

An IRB protocol, however, is far more complicated than a single contractual agreement between an investigator and the institution. It incorporates agreements and authorizations from a broad constituency: department chairs, directors of outside institutions, IRB review panel chairs and administrators, and representatives of the larger society (the "community") from which research subjects may be enrolled into the research. Investigators' qualifications must be established through evidence of prior training in IRB procedures. Further, unless a waiver of consent has been requested by the investigator, each research subject must sign what is essentially a subcon-

[79] *See, e.g.*, Forms for the Northwestern University Institutional Review Board, http://www.research.northwestern.edu/research/oprs/irb/forms/ (last visited Nov. 11, 2006) (all of Northwestern's current paper-based forms can be accessed at this site).

tract—a consent form indicating that the purpose and procedures of the project and the terms of participation have been made clear to him or her; Northwestern further requires the subject to initial each page of the consent form to ensure that nothing has been overlooked. Each project's consent template, since it will eventually generate a separate contract between the university and the research subjects, must be signed and stamped by an IRB administrator. The fact that the other two pillars of *Belmont* concern—risk-benefit assessment and equitability of subject selection—are given nowhere near the attention that the written consent form receives in the IRB system highlights more than anything the overriding legal tenor the entire exercise has taken on.

The fact that so much attention is focused on producing a legally valid IRB protocol, prior to the start of any research, brings to light a puzzle that is too obvious to ignore. If the institution were most concerned about the welfare of subjects in the IRB exercise, we would expect to see equal amounts of attention devoted to all phases of the research, from start to finish. Instead, there is intense emphasis on front-loading: giving highly specified a priori instructions to investigators and securing acknowledgements of risk from subjects. There is virtually no corresponding emphasis on monitoring what transpires once the research begins. Such an oddity yields clues to the main puzzle that underlies the IRB exercise: Where does the institution's priority lie—with the human subject or with the institution? One answer to the anomaly of the heavy front-loading of the research enterprise might be that because monitoring every step of every research project would be impossible, the enterprise must rest on the good faith of investigators to do their studies according to the plan the initial protocol sets out, or to enact changes only by requesting advance permission to enact changes.[80] This seems to us a partial answer. The only answer that makes satisfactory sense is that the front-loading in fact reflects an effort to deflect as much risk as possible from the institution. Drawing a tightly scripted contract effectively follows the "quarantining" model outlined above: it places as much legal responsibility as possible on the investigator, should anything actually go wrong. With this realization, we can understand more broadly the increasing trend among most universities to manage the unexpected by forestalling proactively as many risks as possible, in this case through the instrument of the IRB protocol.

B. Medical

The IRB system is almost invariably described by its critics as deriving from a medical model, one that is wholly inappropriate for the social sci-

[80] Don Workman, the Executive Director at Northwestern's Office for the Protection of Research Subjects, has pointed out in personal conversations that the wording of the institution's contract with the federal government itself—an "Assurance" (Federalwide)—implies that trust is at the center of the agreement.

ences.[81] Traces of the stream toward medical practice are transparent in the Northwestern IRB portal web pages,[82] which administrators have tried to write broadly for the entire research community covered under Northwestern's six IRBs.

Like a medical experiment, the IRB model is oriented to the risk of a Type 2 logical error in medical diagnosis: overlooking statistically rare but highly dangerous events.[83] Even the word "protocol" itself, referring to the IRB document that describes the study and its activities, is taken directly from the language of an experiment or medical trial. Reinforcing the medical conception of IRB, but also drawing on a legal one, is stark warning language, both to the individuals on whom information will be collected in the consent forms they must sign, as well as to investigators. To subjects, these warnings must explain the study's procedure, describe its risks, and point to avenues of recourse if concerns arise. Investigators who encounter instances of possible harm to their subjects that may stem from the study must fill out an "adverse event" form,[84] and they must document deviations from planned procedures with "protocol violation" forms.[85] All such texts imply that the procedure may cause harm and, by extension, that the investigator conducting the experiment is not to be trusted.

Much of the medical tilt to the IRB exercise is inscribed in the regulations themselves, as are a vast array of ambiguities that appear when the model is transposed onto the social sciences. At one point, for example, our

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[81] The definition of research that 45 C.F.R. § 46 set out, and that later revisions embellished, is based not simply on a medical model, however, but a cultural model of mid-twentieth century of medical experimentation. *See, e.g.*, Rena Lederman, *Introduction: Anxious Borders Between Work and Life in a Time of Bureaucratic Ethics Regulation*, 33 AM. ETHNOLOGIST 477 (2006); Rena Lederman, *The Perils of Working at Home: IRB "Mission Creep" as Context and Content for an Ethnography of Disciplinary Knowledges*, 33 AM. ETHNOLOGIST 482 (2006). This model looked out on the world of social science with what we might today see as an exceptionally naïve gaze. *See, e.g.*, 45 C.F.R. § 46.117 (2005) (the handling of informed consent). The Code's attempt to legislate ways by which different forms of science under its jurisdiction should be handled or automatically exempted is revealing as a historical window into science four decades ago. Its treatment of exemption § 46.101, for example, treats methods as inherently risky (or not), a stance that contemporary debates about "essentialism" would question. *See, e.g.*, Shelley Fisher Fishkin, *Essentialism and its Discontents*, 48 AM. Q. 142 (1996) (reviewing ANN DUCILLE, THE COUPLING CONVENTION: SEX, TEST, AND TRADITION IN BLACK WOMEN'S FICTION (1994)).

[82] *See* Northwestern University Institutional Review Board, New Project Submission Form for Social and Behavioral Science (NPSF-SBS), *available at* http://www.research.northwestern.edu/research/OPRS/irb/forms/documents/NPSFBehavioralScience11-02-2006.doc (last viewed Nov. 11, 2006).

[83] For a general description of Type 2 errors, see STEVE MCKILLUP, STATISTICS EXPLAINED: AN INTRODUCTORY GUIDE FOR LIFE SCIENTISTS 97 (2006).

[84] Institutional Review Board, Northwestern University, Guidelines for Serious Adverse Event, http://www.research.northwestern.edu/research/OPRS/irb/forms/docs/SeriousAdverseEventGuidelines.doc (last viewed Nov. 11, 2006).

[85] Institutional Review Board, Northwestern University, Guidelines on Protocol Deviations/Violations (rev. Nov. 12, 2002), http://www.research.northwestern.edu/research/OPRS/irb/forms/docs/ProtocolViolationGuidelines.doc.

social science panel struggled with the issue of "pregnant women," one of the OHRP-defined populations of special vulnerability.[86] If a social science researcher engaged in a project on shopping behavior engaged in conversation with a woman of reproductive age, should the investigator ask if she were pregnant? If just one woman answered affirmatively, would the risk level of the entire study increase? Should every project, in fact, that might involve women of childbearing age ask each woman's pregnancy status systematically? Other disjunctures—or inappropriate mergers—between the medical and social sciences have arisen in the efforts to make policy at local institutions. As late as November, 2005, the FAQs web page of the general Northwestern IRB guidelines posed the hypothetical question, "Who may be a[n IRB] Principal Investigator?," and provided the following response:

> Faculty who conduct research off-site in private offices, and do not submit to ORS [Office of Research Services], are not under Northwestern IRB oversight and may not submit to the IRB for review.[87]

Clearly addressed to medical researchers who do outside consulting and research for organizations such as pharmaceutical industries, this statement sought to extricate Northwestern from the significant university risks such research might entail, and the administrative IRB costs of regulating it. Read at face value, however, this odd moment of slippage denied a large proportion of the social science enterprise the privilege of applying for IRB oversight. When one of us—spotting this ray of hope—communicated to IRB administrators a desire to actually comply with this rule for an off-campus, non-Northwestern financed project, the statement was quickly removed.

Seeing, as we noted above, the problems of treating medical studies and the social sciences as a regulatory package, Northwestern and other universities tried as early as 2000 to help the social sciences by creating separate review channels and sets of protocol forms for the two domains. Despite the now-separate review channels, the language of medical risk continues its penetration into the social science forms and rules. One likely reason is that the enormity of risk that universities take on in sponsoring medical studies means that medically-driven rules and forms, which are written to counter these risks, have remained the default pathways. Less obvious to outsiders are the streams of external advice and directives that

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[86] 45 C.F.R. § 46.203 (2005).

[87] Office for the Protection of Research Subjects: Institutional Review Board, Northwestern University, IRB Regulatory Authority and Governing Principles § I.G, http://www.northwestern.edu/research/OPRS/irb/policies/manual/,section_I.html#I_G (last visited Nov. 21, 2005) (website no longer available, on file with author and *available at* http://web.archive.org/web/20041113172049/http://www.northwestern.edu/research/OPRS/irb/policies/manual/section_I.html#I_G).

local IRB offices receive from OHRP[88] and advice from national professional associations of human subjects protections managers.[89] Less obvious still, but perhaps the most interesting explanation for the persistence of the medical model in IRB regulation of the social sciences, are the demands of insurance underwriters on health providers. Since records used in clinical encounters may be used in medical research, the same means used to protect healthcare providers in an increasingly litigious environment now apply to medical researchers as well, requiring them to use protocols whose language attempts to shield practitioners from liability.[90]

Whatever the source, each new medical defense measure joins an accreting repertoire with an overwhelmingly medical thrust. Unless each new piecemeal demand and advice item is filtered with a highly conscious eye to its implications for a range of disciplines, it heads for the default medical stream of forms and questions that all researchers subject to IRB review must address. The logic of the IRB requirements, together with the escalating legal risk surrounding medicine, ensures the persistence of a medical model for all research involving human subjects. The result is that social science faculty and students find themselves waging a constant battle of writing against the undigested clinical medicalisms that suffuse the IRB protocol.

C. Small-Step Science, Old Research

Although the medical model of research has dominated, our critiques of the IRB-regulated universe point to what may be a better set of descriptors: an activity conducted in small, modest steps, likely under the patronage of someone else. A positivist model of science brings the small-step facet sharply to light. By positivist, we refer to the conviction that the authentic knowledge can only come from affirmation of theories through strict scientific method, which includes subjecting empirical observations of reality to hypothesis testing.[91] While social science research in general acknowledges that wide variability occurs in the world, the positivist model demands control over every parameter except the variable to be manipulated experimentally. Intuitive and compelling to contemporary Western thinking, the positivist, hypothetico-deductive model of science implies a "laboratory," a controlled space with sharply defined boundaries that is

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[88] *See, e.g.*, IRB Member News, http://www.orau.gov/communityirb/news.htm (last visited Nov. 11, 2006); Office for Human Research Protection, Applicability of 45 CFR Part 46 to Clinical Investigations Conducted Under FDA's Interim Rule at 21 CFR 50.23(e) (June 7, 2006), http://www.hhs.gov/ohrp/humansubjects/guidance/invitrodev.html.

[89] *See, e.g.*, Association for the Accreditation of Human Research Protection Programs, http://www.aahrpp.org/www.aspx (last visited Nov. 11, 2006); National Association of IRB Managers, http://www.naim.org/ (last visited Nov. 11, 2006).

[90] Carol A. Heimer, *Risk and Rules: The Legalization of Medicine*, *in* ORGANIZATIONAL ENCOUNTERS WITH RISK 92 (Bridget Hutter & Michael Power eds., 2005).

[91] KARL R. POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY (1980).

used to perform experiments. Here the environment can be held constant to observe variant responses among individual subjects who are exposed to a uniform set of test conditions through standardized encounters with a single researcher.[92] In contrast to inductive research, which requires wide boundaries of possibility and can take many false starts, positivist science asks a single yes or no question and receives a single answer. Perfectly geared to Popperian hypothesis testing, this model of research confines gains in knowledge to small deductive increments, one cautious IRB protocol authorization at a time.

If the positivist model of research is one that moves slowly, another facet sums up the enterprise in terms of the claims to innovation such a model allows. The inescapable descriptor here is "old" research. Since any new project that comes to the IRB must go through a review that scrutinizes it afresh and may require revisions, much time and effort must be spent preparing each new project and waiting for approval. Changes or "revisions" in existing projects, by contrast—and "renewals" of old projects—can be written and evaluated quickly, and they tend to go through review much more perfunctorily. Students and colleagues who can be attached as study personnel to extant projects with previously approved protocols designed by someone else possibly years ago can begin work quickly, and they can disseminate results. In part, this model reflects national trends in funding big-science projects, often requiring intensive investment in physical facilities, rather than small original projects designed by individuals. Whatever the impetus, the tremendous investments of time and effort that protocols for new work require create a situation that favors individuals who are willing to work off the established templates of projects that already have approval. As a pragmatic strategy, then, an apprenticeship or clientilistic model of research may be the preferred IRB default for anyone hoping to do anything more than "unsystematic" or "ungeneralizable" work, especially for those with little wherewithal to take the research initiative.

Our investigations, based largely on cumulative and collective memory, as well as on recent communications with colleagues, have focused almost exclusively on the social sciences. But the realization that within the social sciences themselves there are crucial differences, most notably those between faculty who orient to a lab versus a "naturalistic" setting, has spawned a number of questions in our minds about the possible chilling and distorting effects of IRB regulation on the biomedical sciences as well. Biomedicine and the social sciences are usually seen as having distinct if not opposed interests in IRB matters, with the power of biomedicine almost invariably swaying policy to the disadvantage of social sciences. Certainly,

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[92] *See* Lederman, *The Perils of Working at Home*, *supra* note 81, at 484–85 (on the IRB–medical model's assumption of tightly controlled research space in an environment controlled exclusively by the researcher, as opposed to one often controlled more by the "subjects," as ethnographic work requires).

biomedical protocols read much as their usually positivist research proposals do. We have come to suspect, however, that there may be more in common between the two enterprises' IRB dilemmas than has been appreciated. Biomedical scientists may appear to better fit the IRB model, but they are held to the details of tight protocol procedures. Moreover, as one senior medical researcher argued, if social science research is forced increasingly into secondary and tertiary analyses or extant data sets, such may be even more the case for biomedicine.[93] Current IRB demands and time constraints would make it nearly impossible for a medical student to do an independent project. Social science research (particularly naturalistic research) may be chilled, distorted, and forced into routinizing languages of compliance, with its students able to do projects but not to disseminate them. Biomedicine, on the other hand, can publish results, but, as is the case with laboratory-oriented social scientists, the tradeoff is that most research activity, particularly that of young researchers, must occur under an IRB umbrella of existing projects.

VII. DOES IRB REVIEW PROTECT HUMAN SUBJECTS?

To this point, we hope to have made the case that the IRB system has damaging effects on the research output of investigators, no matter how much its representatives try to help investigators. Of course, the *Belmont Report* itself saw the evaluation of research projects as a system of tradeoffs, balancing risks to human subjects against the benefits that accrue from research performed on those subjects.[94] Therefore, it would not be appropriate to restrict the tally only to research productivity. We should also ask whether that loss in productivity has bought more ethical treatment of research subjects. While the impossibility of controlled-comparison conditions forecloses a direct answer to this question, there are numerous suggestions that the effects of the IRB on ethics are not entirely positive. In fact, the IRB system may be negatively affecting the safety of individuals who participate in research. It is here that we encounter what is perhaps the most disturbing manifestation of the effort to regulate creativity.

First, and most concretely, the IRB system can directly create risks for subjects. Some of the most unsettling potentials of IRB arise in the written consent forms used by most universities. While the consent form in theory provides a check on the investigator, it is not understood in this way either by most subjects or by most investigators. Rather, it is a tool the university may use if a lawsuit should arise. Evidence that consent forms themselves pose risk surfaced in the only Northwestern case we know of in which risk managers and lawyers were asked to sign consent forms for a graduate student who wished to interview them about their work. They were happy to

[93] Email from Thomas Schnitzer, Member, Northwestern IRB Advisory Committee, to Caroline Bledsoe, Professor, Northwestern University (Sept. 23, 2006, 22:35:40 CST) (on file with author).

[94] BELMONT REPORT, *supra* note 20, at 23,195–96.

be interviewed, but refused to sign her consent forms because they realized full well the implications of the forms' contents. They feared, among other things, that their study responses, which would cover their financial dealings, could be inspected in the future by a range of people, as Northwestern consent forms stipulate,[95] including university officials, who, these subjects feared, might turn the information over to fund raisers.

Information contained in consent forms is exposed to more direct risks in other situations. IRB regulations assume a stable, secure place to keep consent forms. All this is in question when consent forms must travel or be created in a difficult political environment. We do not know the extent to which Homeland Security officials have access to university records.[96] But the rapidly developing surveillance technologies and policies will very likely facilitate the inspection or even the monitoring of IRB study records. The move to electronic IRB systems, as much as they may facilitate study approval, could hold the potential for great risk to subjects. An informal legal opinion on this suggests there is no reason why IRB information would not be subject to an administrative or other subpoena. OHRP has encouraged IRBs to require researchers to get so-called certificates of confidentiality in order to bar legal requests for information from researchers.[97] But IRBs and those licensed by them are as much subject to law as anyone else, and it is difficult to imagine that any federal court would hesitate to require an IRB to turn over the information expected from any other individual or institution.

In international settings, the signed consent forms that researchers must bring back to the U.S. and retain for IRB purposes could create disaster if written consent forms fall into the wrong hands. For off-site projects, consent forms in a checked luggage item that ends up missing from a flight will be lost, and any item at all is now increasingly vulnerable to inspection by security guards at any airport in the world. IRBs allow investigators to ask for a waiver of written consent in these circumstances, but investigators cannot predict what may happen in such situations before it is too late, and some have been reluctant to ask for a waiver since a rejection of the request could delay their project's approval.

The censoring effect of IRBs itself appears to lay additional grounds for creating risk to new populations of participants, by forcing research outward and away from strictly regulated domains toward "more relaxed regu-

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[95] Office for the Protection of Research Subjects, Northwestern University, Informed Consent Templates, http://www.research.northwestern.edu/research/oprs/irb/templates/ (last visited Nov. 12, 2006).

[96] Sam Dillon and Stephen Labaton, *Colleges Oppose Call to Upgrade Online Systems*, N.Y. TIMES, Oct. 23, 2005, at A1 (article regarding concerns on the growth of the Communications Assistance for Law Enforcement Act, which allows for government to monitor colleges' online communication systems).

[97] Office for Human Research Protections (OHRP), Guidance on Certificates of Confidentiality (Feb. 25, 2003), http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm.

latory environment[s]."[98] Evidence for this is found in the shocking suggestion that "ethics over-regulation" has prompted American institutions, including universities, to outsource clinical trials through "contract research organizations" to the developing world or even into the shadowed world of undocumented immigrants living in the U.S.[99] The aim of these trials is to develop medications that benefit largely those with means. At a minimum, this practice is contrary to the *Belmont* principle of equitably distributing risk.

As the current IRB model has evolved over the last few years, the concept of risk has changed. In the past, researchers had the reasonable expectation that their innocuous research would be approved after appropriate review. This is no longer true. Whereas the focus of IRB should be on reducing risk to subjects, the risk is now the IRB itself. Researchers have now spent several years trying to figure out precisely what is and is not acceptable to the IRB and how to avoid legalistic scrutiny that, at best, wastes time and, at worst, results in censorship. Just as the changes in IRB have changed the meaning of risk, so too have they changed the meaning of protection from risks. A small number of researchers do indeed see IRB as offering protection, but seldom is this seen as benefiting the participants themselves. Instead, the IRB is seen by such researchers as a means of protecting their research from the penalties of the University, the NIH, and the legal system, and the harm that is feared is the budgetary harm and the harm to reputation that would result from shutting down research over violations.

Leaving as little scope as possible for investigators to think for themselves about ethical dilemmas that inevitably arise in the real world, the cage that the IRB system creates pre-empts not just action but thoughtful ethical response. In fact, our impression from our own disciplines is that the entire IRB enterprise appears to have suppressed talk about real research ethics. Concern for IRB policing suppresses the voices of educators who try to train students to grapple with issues of great social or ethical moment. Indeed, discussions between investigators and IRBs are rarely, in our experience, focused on topics of real ethics. Despite the Northwestern IRB office's effort to shift to a mentality of service, it has not been possible to escape an ideological environment in which the university, the researcher, and sometimes the subject are adversaries. The stronger the IRB's need to protect the university from lawsuits and loss of NIH funding, the more diminished a genuine concern becomes for those who participate in research. As happens in any bureaucracy, the true goals can ultimately be displaced;

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[98] Mahadev Murthy, *Clinical Trials in India: Current Trends and Future Opportunities*, REG. AFFAIRS FOCUS MAG., Aug. 2006, at 10, 10.

[99] *See, e.g.*, Posting of Stuart Rennie to http://blog.bioethics.net/2005/08/is-your-country-attractive-for.html (Aug. 19, 2005); Paul P. Brown, *What's Offline: Outsourcing RX*, N.Y. TIMES, Mar. 11, 2006, at C5; PBS Capsule on Episode Regarding Medical Testing on Humans, http://www.pbs.org/wnet/air/episodes_102.html (last visited Nov. 12, 2006).

in this case, the IRB may be displacing ethics in pursuit of the goal of following its own procedures.

Pondering these paradoxes in the blurry world of bureaucratizing ethics, it occurs to us that today's graduate and undergraduate students must confront a bizarre world of research ethics. They are faced with the implicit claim that IRB expectations of research conduct represent the highest standard of ethics. As they will quickly discover, however, the same ethical standards that their faculty mentors convey to them one month can somehow become substandard in the next month. They will also discover that not only do specific IRB configurations of regulatory demands change rapidly in their own institution, but such demands vary considerably across institutions. The inescapable message is that ethics is yoked to their institution's changing needs, and not to the situations they actually will confront. Our acts of providing students with safe formulations to secure IRB approval, however, may serve more than anything to demonstrate to them that the IRB is anything but an infallible arbiter of universal human ethics. The enormous weight of the IRB model gives students few benchmarks against which they can compare what they can do in their disciplines today against what their disciplinary forebears did. Students sometimes express confusion to us at how previous generations of researchers whose achievements they read about could conduct these studies, or how their disciplinary ancestors could contribute their research materials to the university archives in a way that they themselves will not be able to do. The strength of the IRB fortress that is gradually encrusting their disciplines must further imply to them that the world is fraught with the kinds of dangers surrounding "others" that the IRB codifies. Reflecting our own cultural phobias about vulnerable groups and those that experience discrimination, such codifications are inscribed into the very language of the contract that students must enter into.[100] IRB phobias even extend to systematicity itself, which we try to tell students is the central responsibility of anyone who claims to make public statements about the nonfiction world. IRB phobias extend, finally, to the students themselves. It can only become common sense to students that they are unqualified to address certain populations or topics or to use certain methods without subjecting their intentions to higher authorities for ethical judgment. To the most thoughtful students, it must seem as if intelligent reflection on research ethics is not possible.

CONCLUSION

One could scarcely imagine a better example of a bureaucracy of the kind that so fascinated and infuriated Weber than the contemporary IRB system. To practice their trade, researchers must comply scrupulously with voluminous rules that allow the narrowest range of conduct, only after gain-

[100] 45 C.F.R. § 46, at subpts. B–D (2005) (subparts pertaining to extra protections for prisoners and children).

ing advance permission for each step they take. Since the demands of this burgeoning and contradictory system are impossible to meet, IRB representatives must spend increasing amounts of time with each individual researcher and continually devise ever-more elaborate efforts to ensure compliance. Exactly as Weber would have predicted, the bureaucracy, committed to rigid notions of compliance, creates for itself a continuous stream of what constituents and members alike see as nuisance: something to avoid and create shortcuts around or pathways through. Rather than developing an appreciation for the deeper concerns from which the institution arose, both sides displace their own goals and come to value instead the efficiencies their leaders create that might allow them to be compliant. As the IRB iron cage closes in, squeezing research that presents itself for review into medico-legal expressions of "old" research, the core of the university spirit is placed on the defensive. Flattened and drained, regulated creativity becomes reduced to increments of knowledge by tiny, measured steps. And if IRB-compliant research must be modest, its teaching must be guarded. The most serious damage, in fact, that the demand for advance permission to do research wreaks may be its impact on training the next generation of researchers.

Under the press of the IRB, social scientists in the U.S. increasingly find themselves on the defensive. They are at the mercy of a legal system that is written, and continues to be adapted, largely for the purpose of biomedical regulation. They are faced with requirements that start from a presumption of danger, forcing them to take extra steps to ask for exemptions and waivers for benign activities. Worse, they are obliged to cast innovation—the very thing the university hired them to produce—as revisions and protocol violations. The response to the risks posed by IRB is to restrict research to "safe" levels: to write protocols that promise to be exempt, that avoid vulnerable populations, and that skirt difficult topics. Particularly the research of students is penalized. To avoid IRB's burdens, mentors must increasingly choose between defining their students' research as "non-research"—i.e., non-systematic, non-generalizable, and hence not allowed to be published—or grafting it onto their own protocols for IRB umbrella protection at the cost of personal credit to the students. The result is an adversarial system that encourages perfunctory compliance, to the point of gamesmanship, rather than a thoughtful approach to protecting subjects.

The quagmires of the IRB system generate many ironies. Among them is the fact that it is often the demand for regimentation itself within a narrow bureaucratic rule corpus that allows the research to go on, especially, as we have argued, in the cracks of what practices such as consensual censorship can open up. Investigators and the IRB must engage in such practices, we believe, because under the current IRB press that most universities face, the only way for any research progress to be accomplished has been the mutual agreement to avoid certain topics of discussion and to word submissions and reviews in ways that incorporate the strict regulatory language.

While clear gaps result, the most notable are the research practices that actually matter in the "real" world outside of—or buried in the interstices of—the IRB system. To the extent that consensual censorship exists, genuine concerns about risk and ethics are likely withheld from discussion through IRB formal channels. To the extent that the IRB system should in fact act as the arbiter of ethics in the university, this facet blunts the ability of the system to carry out its stated goal of affording protection to research subjects.

Presenting truly conclusive evidence, of course, for the scale of the chilling and distorting effects of IRB on research would be impossible. Doing so would require trying to compare a present reality with a host of absences: of "deterrence" paths not taken. These might include the undergraduates diverted from original research toward a library thesis, the research grants not written, the decision to devote a career to studying union workers rather than children, the decision to avoid majoring in a field in which an honors thesis can be disseminated without IRB review, or the choice of a graduate field that will not require IRB oversight. The point of more serious concern is that in our assessment, debates about both the IRB definitions of ethics and of the constraints on research that these definitions are used to justify seem far less visible than they were even several years ago. Taking their place are increasingly routinized configurations of regulatory procedures—and their concomitant loopholes and pathways through the obstacles. Most investigators alter their research and teach their students in ways that appear to be accommodating to the IRB facts of life in increasingly taken-for-granted ways. Displacement works in many ways and through many agents.

The fact that we are left with highly constrained visions of the researchable world—and that the language for describing it has so little relation to reality—is unintended. No one set out to build a bureaucracy that crushes imagination. However, adherence to IRB regulations increasingly places the most valuable products a university can generate, research and teaching, in the hands of an institutional structure whose primary interest is ensuring adherence to a set of increasingly misguided readings of a major ethical legacy. Doing so not only puts subjects, projects and careers at risk—it also risks a serious distortion of the university mission.