

“Turn off the oxygen . . .”

Robert Dingwall

Malcolm Feeley’s Presidential Address ranges widely over the current condition of law and society studies. However, as he himself acknowledges, its core is the critique of institutional review boards (IRBs). Although there have been growing rumbles of discontent, he is one of the few senior scholars to step out of line and fundamentally challenge the system. He indicts the entire IRB structure for regulation without legality, unconstrained by any acknowledgment of public accountability, the rights of investigators, or due process. This is an important critique and has implications well beyond the borders of the United States. However, I am not wholly convinced by Professor Feeley’s resistance strategy.

I want to preface my response with an explicit statement of support for the principle of ethical regulation in some areas, a position with which Professor Feeley would not, I think, disagree. However, this is not clearly articulated in his speech, and I believe that it is essential to stress that neither of us are ethical nihilists. Certain kinds of experimental research in biomedical science and psychology have an indisputable potential for harm that cannot necessarily be identified when subjects are recruited and that cannot easily be reversed once the study has begun. In March 2006, for example, six British men experienced multiple organ failure as a result of the administration of TGN1412, an experimental drug, in a clinical trial unit attached to Northwick Park, a leading research hospital in London. All survived but have suffered long-term health consequences. Although subsequent investigation revealed a number of procedural lapses, none were relevant to the outcome: in the areas that mattered, regulatory clearance, including the equivalent of IRB approval, had been obtained and observed. Participation in biomedical research carries very serious risks. When the stakes are so high, it is entirely proper that investigators should not be judge and jury in their own cause.

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Independent review provides a means of ensuring that an adequate risk analysis has taken place, that reasonably foreseeable risks are clearly communicated to participants, and that there is no improper pressure to take part. If there is still an adverse outcome, the public can be assured that this was caused by an unforeseeable risk that was voluntarily accepted by participants.

These arguments do not apply to most empirical research in the social sciences and humanities. This work is not comparable with injecting potentially toxic green stuff that cannot be neutralized or rapidly eliminated from the body if something goes wrong. There may be some potential to cause minor and reversible distress, but these disciplines' strong traditions of protecting the identity of informants and research sites limit the risks of serious harm, which would, in any case, be mostly reputational. While it is possible that some criminologists might place their informants at risk of reprisals, there is no documented case of this happening. Moreover, at least some of that risk is shared by fieldworkers: "James Patrick" (1973) chose to publish his observational study of a Glasgow gang under a pseudonym because of his own fear of attack by discontented members. Consent is an ongoing process and may be suspended or withdrawn at any time. Any experienced social scientist has had informants terminate interviews or fieldwork access because they do not feel comfortable with the direction of inquiry. When that happens, we cannot compel compliance: we are not agents of homeland security.

The International Significance of IRBs

Professor Feeley's critique should attract wide attention because of the international impact of U.S. developments. This takes two forms: the extraterritorial claims of U.S. legal institutions and the isomorphic pressures that arise from U.S. cultural hegemony.

Those of us who live and work outside the United States have long been familiar with the American claim to universal jurisdiction. In the United Kingdom, for example, we are witnessing the consequences of a one-sided extradition treaty, signed by the Blair government, that removes most safeguards on the transfer of British subjects to the United States but offers no parallel fast track for the transfer of U.S. citizens to the United Kingdom. Although its ostensible targets are international terrorists, the main victims have been hapless executives on the fringe of U.S. corporate scandals, accused of offenses that may not be crimes under U.K. law. It is not surprising, then, that IRBs tend to make the same claims, demanding jurisdiction over any researcher with whom any U.S. scholar collaborates. I have recently been engaged on a small

project, based entirely on interviews with public officials, with a colleague from another European country and a colleague from a large U.S. state university with a high research profile. All the direct funding was from the European side, but the IRB sought to review the whole project, to scrutinize both European partners, and, at one point, to require both of us to take their online course in research ethics as a condition for allowing their faculty member to participate. We wrote firm letters to the IRB, pointing out that our research met the prevailing requirements in our own countries, and the board backed off: we did not, of course, state that both countries, at that time, thought it unnecessary to regulate investigators so that compliance with “prevailing requirements” simply meant our professional consciences. I am not entirely comfortable with the deception: on the other hand, when dealing with an institution whose legitimacy is questionable, I am not sure that there is a moral obligation to deal with it on its own terms. I certainly resent the need to trouble my conscience with such subterfuges.

These direct encroachments are, however, rare, because there are relatively few such collaborations. The cultural dominance of U.S. biomedicine imposes more insidious isomorphic pressures. An important export route for the IRB model has been the control of access to scientific publication. Unless biomedical research has been approved by an IRB-type body, it cannot be published in any major journal. Most leading research countries, and many lesser ones, have installed such systems in order to maintain their access to the international scientific community. Having created IRBs to deal with biomedical work, there have been inevitable conflicts with social scientists working in health care, whose studies have fallen foul of different disciplinary understandings of method, risk, and process. There has also been the kind of jurisdictional expansion seen in the United States, where scientific and biomedical interests have seen an opportunity to increase, or entrench, their influence on universities and research institutions, and governance staffers have seen opportunities to generate extra resources, enhanced status, and higher-graded posts for themselves.

In the United Kingdom, pressure from social scientists on the Economic and Social Research Council (ESRC) for support in conflicts with the National Health Service research governance process has had the paradoxical result of generating ESRC demands that universities should introduce comparable regulation. This is partly the result of mimetic deference by ESRC toward more-prestigious biomedical research funders and partly uncritical normative isomorphism, that more governance is necessarily better than less. Although the original ESRC proposals were watered down by pressure from influential researchers, U.K. universities have tended to over-comply in the same way as their U.S. counterparts. The

ESRC (2005) framework allows universities to create self-certification regimes, based on reflective professional practice. However, most institutions have set up campus-wide ethical committees with professional secretariats. These have led to problems similar to those identified in the United States. These committees have also sought universal jurisdiction. At one U.K. university where I recently spoke on these issues, a researcher described how he had been welcomed and facilitated in carrying out fieldwork in a large factory in an Asian country. He wanted to conclude this study by formally interviewing the plant management, but he was required to obtain signed consent for this. The managers were grossly offended by this implied lack of trust and disrespect. The interviews produced meaningless data, and his access to the plant was withdrawn. As he put it, a high-trust society had been polluted by the low trust of the Anglo-Saxon world. Did we really have the right to export our own social pathologies?

The Perverse Consequences of IRBs

It is ironic that the increased regulation of social science and humanities research has coincided with the rise of a surveillance society, where citizens' privacy is routinely invaded in far less respectful ways. Participant-observation may be dying at the hands of philistine IRBs, but CCTV observation of both public and semi-private spaces is constantly expanding. Homeland security agencies are assembling vast unregulated databases of identifiable and sensitive information. Journalists regularly use deception in pursuit of stories, whether of celebrity trivia or serious wrongdoing. A good example, cited in Professor Feeley's address, is the work of Barbara Ehrenreich, whose recent books, *Nickel and Dimed* (2001) and *Bait and Switch* (2005), made the *New York Times* Bestsellers list for their explorations of the conditions of low-wage employment and of redundant middle-managers, respectively. However, both depend on covert research, where Ehrenreich faked CVs and references to conceal her identity as a journalist and social investigator. They are widely assigned to undergraduates in the United States and held up as examples of the sort of interesting books that social scientists *ought* to write—but neither could receive IRB approval. IRB regulation has become a smokescreen behind which our rivals in social investigation and commentary can proceed unchecked, while those of us whose practice is disciplined by a professional ethic and a regulative ideal of truth-telling are handicapped in our access to the public realm. By picking on a politically weak group—academics—it *appears* that concern is expressed for citizens' rights, while security and corporate interests can range unchecked.

Another irony is the determination of IRBs to overprotect citizens who do fall within their jurisdiction. Historians and political scientists routinely interview people who are happy to speak on the record: indeed their motive for cooperation is often precisely a desire to document their version of events for posterity. This is reinforced by journal editors' deference. Another U.K. case I have collected involves an oral historian who had completed a study of community health activism before the introduction of ethical regulation by his university but was then compelled by a major journal to anonymize his report against the wishes of the activists that he had interviewed (Smith & Nicolson 2007). This overprotection extends to so-called vulnerable groups. There is something slightly odd about the scale of activity devoted to empowering people with learning disabilities, for example, while simultaneously denying them the right to make their own decisions about being interviewed. Clearly, their intellectual limitations may be important in understanding the risks of a complex biomedical experiment, and protection is appropriate to avoid some of the past abuses documented by Rothman (1993). However, I have not found reports of people in this category having difficulty in refusing to participate in social research that makes them feel uncomfortable.

Unfortunately, such observations tend to sound like whining about the unfairness of the world and are not, in my view, a very persuasive argument for those whose support will be necessary to roll back ethical regulation. They invite the response that the solution is to regulate everyone equally and that we should just see ourselves as the first in line rather than the fall guys.

Do Investigators Have Rights?

Because of the problem with the arguments about fairness, the emerging argument about First Amendment rights is an attractive one. If preemptive regulation of research by IRBs can be defined as licensing speech, then the courts could be used to enforce a right regardless of whether the academic community could win the political battle for stakeholder opinion. However, there are serious problems with this strategy. First, although there is some persuasive writing by academic lawyers on the subject, this does involve the extension of existing jurisprudence and it is by no means certain that the courts would follow the same reasoning. Second, as law and society studies repeatedly remind us, rights are not self-enforcing. Suppose a *casus belli* could be found, or manufactured, whose pockets are deep enough to pursue the action? Probably not those of any private individual or most disciplinary associations. Finally, there are the complex relationships between the higher

judiciary and the political culture of the times. Is the current Supreme Court really so devoted to the First Amendment and respectful of the academy that it could be relied upon to produce a favorable decision?

Moreover, this strategy is not helpful to those of us whose human rights legislation is less forthright than the U.S. Constitution. Compare the First Amendment with the parallel clause (article 10) in the European Convention on Human Rights:

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. . . . The exercise of these freedoms . . . may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests . . . the protection of the reputation or the rights of others, for preventing the disclosure of information received in confidence . . .

The European version is far more hedged and offers greater scope for prior restraint. Free speech in Europe is not such an absolute as in the United States. A litigation-based strategy has much less to commend it in such an environment. It also has echoes of special pleading—that we cannot win a political argument but must look to the courts for protection.

What Are the Costs of Regulation?

For this reason, I am more attracted by the search for arguments based on interest rather than rights. Can we demonstrate that the social costs of regulation exceed whatever private benefits this confers? If we are to make this argument, we need to return to fundamental issues about why freedom of inquiry matters in democratic societies. I think that this argument may have three elements.

The first is quite narrow but far-reaching. It acknowledges that a great deal of social science research is funded by governments to determine whether tax revenues are being spent efficiently and effectively, and, at least in European social democracies, equitably and humanely. This forms part of the government’s contract with taxpayers: that tax demands will be kept to the minimum necessary to achieve public service objectives, and that public services will

achieve the objectives for which they are designed. If this cannot be demonstrated, taxation becomes extortion. When IRBs obstruct social science research of this kind, they are interfering with this basic contract between government and citizens. For example, a colleague and I were recently *commissioned* by the U.K. Patient Safety Research Programme to study the incidence and prevalence of the reuse of single-use surgical and anesthetic devices, and to consider why this practice persisted in the face of strict regulation. To comply with the NHS equivalent of an IRB system, we would have needed approval from more than 300 committees, generating about 1,600 signatures, and around 300 health examinations and criminal record checks for my colleague. As a result, we were unable to carry out the study as commissioned and delivered a more limited piece of work (Rowley & Dingwall 2007). Other estimates suggest that the practice we were studying leads to about seven deaths every year in the United Kingdom. The cost of the NHS research governance system can be measured by the lives that will not be saved because our study could not investigate the problems of compliance as thoroughly as it was originally designed to. Moreover, U.K. tax revenues are clearly not being spent appropriately since the health care system is killing or injuring people it is supposed to be benefiting: this is not an effective use of the funds that have been redistributed from private citizens to achieve public goals. We should, then, see both research commissioners and at least some citizen groups as potential allies in resistance to overreaching by ethical regulators.

Second, this narrow case may be capable of extension to consider the wider issue of the role of trust in democratic societies. This has been a recurrent theme in social and political theory for the last 2,000 years. In small-scale societies, trust may be sustained without a specialized cadre of auditors or investigators. In the contemporary world, citizens depend upon a great deal of expert knowledge in order to make good judgments about each other and about the social institutions that they encounter. The quality of that knowledge depends crucially on free competition between information providers. If what has traditionally been the most disinterested source of information, the academy, becomes systematically handicapped in that competition, then all citizens lose out. When we give up doing participant-observation with vulnerable or socially marginal groups because of the regulatory obstacles, then a society becomes less well-informed about the condition of those whom it excludes and more vulnerable to their explosions of discontent. How helpful is it when the only ethnographers of Islamic youth in the United Kingdom are undercover police or security service agents?

Finally, and perhaps more apocalyptically, there is the argument that societies that overregulate speech and ideas ultimately

ossify. The great English sociologist Herbert Spencer (1876) drew an important contrast between industrial and militant societies. The latter, which are well-exemplified by the former Soviet Union and its East European satellites, were, he argued, doomed to lose out in global competition because their authoritarian structures blocked diversity and innovation. Both socially and economically, they were frozen by their command systems. IRBs begin to look like the precursors of the surveillance states that are being increasingly entrenched in the United States and the United Kingdom. Their incursions into liberty are justified in the name of security but may well have unanticipated consequences in terms of prosperity. Wherever dissident voices are silenced, innovation eventually dies.

Theoretical arguments like this need a more popular framing to carry wide appeal. However, it seems to me that if we can show that ethical regulation does not actually contribute to a better society, but to a waste of public funds, serious information deficits for citizens, and long-term economic and, hence, political decline, then we may have identified a set of arguments that might lead to a more skeptical approach to the self-serving claims of the philosopher kings who sustain that system.

So What Is to Be Done?

If the arguments I have sketched above are to win hearts and minds, they clearly need considerable development and refinement. But there are some practical and immediate things that we ourselves can do, which complement Professor Feeley's vision of a legal strategy. We must continue to challenge the legitimacy of IRBs—as the neo-institutionalists remind us, legitimacy is the oxygen of organizations and its denial will ultimately asphyxiate them. We should refuse to service them or support additional university resources for them. We should be explicit with research funders about the way in which the scientific validity of our work is being distorted by ethical regulation: funders are committed to supporting high-quality science and are potential allies if they see that this goal is being systematically compromised, particularly if they are disbursing tax dollars. Our journal editors should resist pressure to demand IRB approval as a condition of publication but encourage authors to explain how their work had been weakened or perverted by IRB requirements. Journal pages are precious, but we have an obligation to use them to expose the pressures to do second-rate science, particularly to substitute safe interview methodologies for direct observational data. If we become disciplines that only study what people say, as opposed to what people do, we

really might as well pack up and leave everything to the journalists and the novelists. *Soyez réaliste, demandez l'impossible.*

References

- Economic and Social Research Council (2005) *Research Ethics Framework*. Swindon, United Kingdom: Economic and Social Research Council. http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf (accessed 16 May 2007).
- Ehrenreich, Barbara (2001) *Nickel and Dimed: On (Not) Getting By in America*. New York: Henry Holt.
- (2005) *Bait and Switch: The (Futile) Pursuit of the American Dream*. New York: Henry Holt.
- “Patrick, James” (1973) *A Glasgow Gang Observed*. London: Methuen.
- Rothman, David J. (1993) *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New York: Basic Books.
- Rowley, E., & R. Dingwall (2007) “The Use of Single-use Devices in Anaesthesia: Balancing the Risks to Patient Safety,” 62 *Anaesthesia* 569–74.
- Smith, Graham, & Malcolm Nicolson (2007) “Re-expressing the Division of British Medicine under the NHS: The Importance of Locality in General Practitioners’ Oral Histories,” 64 *Social Science & Medicine* 938–48.
- Spencer, Herbert (1876) *Principles of Sociology: Vol. I*. London: Williams and Norgate.

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