

Institutional Review Boards (IRBs), mandated in the United States for all federally sponsored research, have increased in number and scope in recent years, with many institutions requiring their IRBs to approve research not specifically mandated by federal regulation. As such, they provide an excellent opportunity to examine the interaction of multiple institutional logics and the legitimation of new and changing institutional practices. In particular, I hope to extend theoretical and empirical research on institutional legitimacy to address the question: How do changes in the scope of an internal regulatory body's authority affect its perceived legitimacy in institutional environments? This proposal outlines that research and is arranged as follows. First, it recounts the history of IRBs and human subject protection. Second, it frames the issue from the perspective of institutional theory and, specifically, legitimacy, marrying that perspective with the literature on professions to extend current discussions of legitimacy by introducing the concept of scope. This section ends with three hypotheses. Finally, I have a very brief outline the methods by which I hope to empirically test this work.

Background on IRBs

The harsh realities of unethical and even criminal activities perpetrated in the name of science during the mid-to-late twentieth century spurred international response. The Nuremberg Code of 1947 and Declaration of Helsinki first adopted in 1964 can be traced directly to the atrocities committed upon prisoners in Nazi concentration camps in the name of science. In the United States, which was a prime sponsor of the Nuremberg Code but not a signatory of the Declaration of Helsinki (Zimmerman, 1997), these codes did not precipitate legislative or regulatory action until after public disclosure of the Tuskegee Syphilis Study in July of 1972 (Heller, 1972). In 1974, the United States Congress passed the National Research Act which

mandated the creation of Institutional Review Boards. Revised twice since then, in 1981 and 1991, federal regulation of sponsored research is now encoded in Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46), “Protection of Human Subject” which has generally come to be known as the Common Rule.

Concurrently, the National Research Act also created the National Commission for the Protection of Human Subjects and charged it with identifying “the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects” (The Belmont Report, 1978). While the Common Rule provides for the regulatory functioning of IRBs, the commission’s Belmont Report provides the “analytical framework that will guide the resolution of ethical problems arising from research involving human subjects” (The Belmont Report, 1978).

Perhaps because the initial incidents which triggered action at both the international and national level were related to biomedical research, or because the risks associated with such research were more immediately obvious, the major focus of early work of IRBs and regulated by the Common Rule was on biomedical research. More recently, both the federal government and individual institutions have been expanding the scope of IRBs to include an increasing array of social science research. This expanded scope has threatened the perceived autonomy of academics in these more recently encompassed fields (AAUP, 2000). The matter is further complicated by the fact that many institutions are expanding the scope of the IRBs to include not only federally sponsored research, but all research.

Institutional Theory and Legitimacy

Institutional Theory has evolved considerably in the past 50 years. Initially focused on the correlation of value and power (Selznick, 1957; Stinchcombe, 1968), the works of Meyer and

Rowan (1977) and DiMaggio and Powell (1983) shifted focus to the isomorphic forces exerted on organization from the institutional environment. This “neo-institutional” theory evolved from how organizations adopt legitimated forms to how they adapt to changing environments (e.g., Hoffman, 1999) to how they employ agency in constructing their institutional environments (e.g., Greenwood & Suddaby, 2006). Common to all of these conceptions of institutions, however, is the construct of legitimacy and the process of legitimation. As a process, legitimation traces its roots to Berger and Luckman’s (1967) treatise of the social construction of reality and describes how institutions evolve from patterns of repeated action through externalization, objectivation, and internalization to become taken-for-granted. As a construct, legitimacy has received systematic treatment in both sociology (Stryker, 1994) and organization studies (Suchman, 1995). In particular, Suchman (1995) outlines three major categories of legitimacy: pragmatic legitimacy based on exchange and influence; moral legitimacy based on appropriate structures, processes, and outcomes or charismatic leaders; and cognitive legitimacy based on either being taken-for-granted or comprehensible.

As IRBs are mandated by federal regulation, their existence at research institutions can be accounted for by what DiMaggio and Powell (1983) refer to as a coercive isomorphic force. An institution that does not establish an IRB is not eligible for any of the billions of dollars the federal government invests in research. As such, the establishment of IRBs that meet the minimum criteria of 45 CFR 46 clearly represents an attempt to gain pragmatic legitimacy. But, as the scope of these boards expands beyond what is explicitly required, many institutional actors, especially researchers who might not otherwise be affected, begin to see the extended scope as a threat to their academic freedom (AAUP, 2000). On the other hand, it is unlikely any of them would suggest that protecting the rights of human research participants should only be a

concern if the research is federally funded. As a consequence, there are conflicting institutional logics, based on conflicting forces of legitimacy, at play in the environment. (For example., the taken-for-granted nature of professional autonomy and self-regulation may appear in conflict with the moral legitimacy of establishing appropriate procedures for ensuring human subject protection.)

One issue particularly salient in institutional environments is that of the role of professions. In fact, DiMaggio and Powell's (1983) normative isomorphic forces were originally theorized to be a direct result of professionalization and professional education. Likewise, current work in understanding conflicting institutional logics looks specifically at how the role of professions impacted the legitimation of a new organizational form (Suddaby & Greenwood, 2005). Various attributes of professions have been proposed, including jurisdiction control, autonomy and authority (Greenwood, 1957). As such, the expanded scope of IRBs undertaken at many universities may be seen as infringing on the professional status of academic research (AAUP, 2000).

I believe institutional factors will dramatically affect individual researcher's attitudes towards IRB processes. In particular, I will attempt to test the following three hypotheses. 1) The more closely aligned a researcher's field of study is to those for which IRBs were first mandated by federal regulation (i.e., biomedical research), the more likely she will perceive the IRB's procedures as legitimate. 2) Perceived illegitimate (e.g., not federally mandated) restrictions on academic freedom will negatively impact researchers' attitudes towards IRB processes. 3) The relationship between a researcher's perceptions of the legitimacy of the IRB and his attitudes towards the IRB will be moderated by the nature of research being conducted. Specifically, researchers typically engaged in invasive or high-risk research will more willingly

accept IRBs with expanded scope than those whose primary research methodologies are minimal risk.

Empirical Testing

To test these hypotheses, I anticipate a multi-method analysis. The first phase would be a survey of researchers across multiple institutions. Ideally, I would focus on a limited number of disciplines to capture variety in terms of the types of research conducted and various methodologies. Present candidates are biomedical, clinical psychology, and management. Similarly, the institutions represented in the survey would include both public and private institutions, and be classified by some indicators of their research activities (e.g., type, priority), as well as the amount of federal funding they receive in absolute dollars and relative to their total research budget. I would also hope to capture variation in the researcher's status (graduate student, as well as untenured, tenured, research faculty). These data would be supplemented by a second, qualitative phase in which I interview a subset of the respondents to gain a more complete understanding of their views and attitudes.

Ideally, the survey would be administered to roughly 500 researchers across 25 to 30 institutions with variation across these dimensions. If possible, I would like to recruit approximately half the researchers from institutions that house all three disciplines and the other half from those which do not, and hope to recruit approximately 10 to 12 researchers from each institution/discipline. Other considerations for variation include geography, both in terms of national culture and also within the United States, but I am uncertain how feasible pursuing either or both of those is.

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