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ABSTRACT: In response to the IRB system for regulating research with human subjects, researchers have raised two apparently contradictory concerns: that IRBs are excessively inconsistent (often raised by biomedical researchers), and that they are excessively standardizing (often raised by qualitative interview researchers). Why does standardization appear as the dominant theme in qualitative researchers' experiences with their IRBs? And how do qualitative researchers experience standardization in their IRB encounters? We focus on IRBs role as regulatory bureaucracies, which typically rely heavily on standardized communication and decisions to process information and make large numbers of decisions in a timely manner. We explore the role of standardization in IRB regulation of qualitative research in an analysis of semi-structured interviews with 26 qualitative sociologists from six research universities and three liberal arts colleges in the Northeastern United States. In a regulatory regime oriented toward the norms of experimental research, these frictions resulted partly from a lack of appropriate standardized language and decision-templates, but also from the inherent difficulties of applying standardized decisions to work that is unpredictable, unique, and difficult to routinize.

In recent decades, "getting through IRB" has become a familiar routine for American researchers planning projects involving interactions with human beings or their identifiable private information (Heimer and Petty 2010). The process usually involves developing a formal description of research plans, or protocol, which is submitted to the local Institutional Review Board (IRB). In the protocol, a researcher must convince one or more IRB decision-makers that subjects will be participating voluntarily, based on a clear understanding of the study and that the benefits of the study outweigh any potential risks.

Researchers responding to this system have raised concerns about two apparently incommensurable problems. On the one hand many studies have observed that different local IRBs arrive at inconsistent decisions regarding the same research proposal, causing significant difficulties for biomedical researchers working across multiple institutions (U.S. Department of Health and Human Services 2011). In the words of one physician and legal scholar: "IRBs [reach] contradictory decisions about identical protocols. When IRBs are so consistently inconsistent….their decisions are not good enough for government work" (Schneider 2015: 83).On the other hand, researchers in the social sciences and humanities, especially qualitative interview researchers, are more likely to charge IRBs with extending homogeneous, biomedical standards to different kinds of research (*see* Halpern 2007; Heimer and Petty 2010; Bradburd 2006; Fassin 2006; U.S. Department of Health and Human Services 2011). As Princeton anthropologist Rena Lederman charges, "the federal system, through local IRBs, [incline] toward applying one homogeneous ethical standard, based on one concept of 'best practice:' a highly idealized model of the 'scientific method' abstracted from clinical biomedicine and experimental behavioral research" (Lederman 2006: 486).

Why does standardization appear to be such a dominant theme in qualitative researchers' experiences with their IRBs? And how do qualitative researchers experience standardization in their IRB encounters? To address these questions, we focus on IRBs role as regulatory bureaucracies, rather than their better-understood role as discretionary committees. Regulatory bureaucracies need to process and store large amounts of information, and make large numbers of decisions quickly. To accomplish this, such bureaucracies typically rely heavily on standardization (Stinchcombe 1959; Galbraith 1977; March et al. 1993). Standardization is particularly indispensable in the regulation of expert work, where it also can lead to unintended consequences (Timmermans and Berg 2003; Sandholz 2012).

We explore the role of standardization in IRB regulation of qualitative research in an analysis of semi-structured interviews with 26 qualitative sociologists from six research universities and three liberal arts colleges in the Northeastern United States. Many of our participants encountered frictions with their IRBs, and we show how standardization contributed to these experiences. In a regulatory regime oriented toward the norms of experimental research, problems resulted partly from a lack of appropriate standardized language and decision-templates, but also from the inherent difficulties of applying standardized decisions to work that is unpredictable, unique, and difficult to routinize. These encounters led some of our researchers to engage in passive resistance, usually by not providing their IRBs with complete information about their research. However, there was also considerable variation. At some institutions our participants were able to work more harmoniously with their IRBs, and this appeared to occur when they encountered IRBs that were less bureaucratic, less reliant on standardized communication, and more open to faculty input.

Regulation and Standardization

Much of the literature on IRBs focuses on their role as committees, made up mostly of faculty volunteers, and charged with making collective ethical judgments about research proposals (Stark 2007, 2012; Schneider 2015; De Vries et al. 2004; Schneider 2015; Pritchard 2011; Stair et al. 2001; Johnson 2008; Fitzgerald 2004). Federal regulations delegate considerable discretion to these committees (Halpern 2007). This has been shown to lead to inconsistent decisions across IRBs, and to create problems for multisite biomedical studies (Stair et al. 2001; Silverman et al. 2001; Dziak 2005; U.S. Department of Health and Human Services 2011; Hirshon and Krugman 2002).

However, IRBs are not just committees; they are also regulatory bureaucracies (Heimer and Petty 2010) that engage in many activities other than full board reviews. To accomplish the manifold, more routine tasks of IRB administration, IRBs may rely on faculty volunteers who have been deputized to behave as bureaucrats "temporarily and for a specific decision-making purpose" (Stark 2012: 4). IRBs also increasingly rely on paid, and increasingly professionalized, administrators (Bledsoe et al. 2007; Schrag 2010). For practical reasons it would be impossibly unwieldy for fully convened boards to make all IRB decisions. Federal regulations allow lower risk research with competent adults to be reviewed as "Expedited" or "Exempt." Qualitative interview research proposals overwhelmingly fall into these categories. Local IRBs administer these protocols in different ways, but one common approach is to have each "Exempt" protocol reviewed by an administrative staff member, and each "Expedited" protocol reviewed first by a staff member and then by single faculty volunteer. Regulations require that IRBs not only make decisions, but also engage in scrupulous documentation of how and why particular decisions were made, and frame this documentation in regulatory language (Heimer and Petty 2010).

To process and store large amounts of information and to make large numbers of decisions in a timely manner—and to avoid treating every case as a special case--bureaucracies famously rely on standardization (Weber 1946; Stinchcombe 1959; Leidner 1993; March et al. 1993). However, bureaucracies in the business of regulating people always contend with the problem that those being regulated control knowledge about the regulated activity (Baron and Besanko 1984). This problem is particularly acute in the regulation of expert work, which is often esoteric and inaccessible to outsiders (Timmermans and Berg 2003).

Literature on medical professions suggests that two varieties of standardization are particularly important to the regulation of professional work. The first is standardized decision-templates, sometimes known in organizational literature as "programs," or "routines" (March et al. 1993; Stinchcombe 1990; *see also* Timmermans and Epstein 2010 on "procedural standards"). These decision-templates provide non-experts with a basis for making routine decisions about professional work—to "pry open the black box of clinical judgment" (Timmermans and Berg 2003: 106). For example, an insurance company employee can compare a doctor's actions against a set of uniform clinical practice guidelines, and thereby decide whether to reimburse.

The second variety of standardization is standardized communication, such as forms and other paperwork. Paperwork is an uninspiring subject--and perhaps for this reason has received little consideration in the standardization literature. Yet standardized communication with authorities is a major feature of modern life, whether we are taking the SATs, filling out a tax form, or applying for a drivers' license. Such communication translates dense, contextual information into a simplified format that can be easily transmitted, stored, and evaluated (Yates 1989; Scott 1998). Standardized communication makes it possible for unskilled decision-makers--or even computer programs--to render judgments For example, doctors are required to

fill out reporting forms, which enables insurance company employees lacking medical training to get information in a format they can interpret (Hafferty and Light 1995; Timmermans and Berg 2003: 67).

Engaging in standardization allows regulators to pursue important social goals. Most of us are grateful, for example, that the U.S. FDA enforces safety standards for our food and medicine. All research with human subjects—including social research—poses ethical dilemmas for which researchers should be held accountable. However, regulatory standardization is not necessarily cost-free. Professionals typically object to both regulation and standardization, which represent intrusions on professional autonomy (Friedson 1994; Abbott 1988). Yet professionals may also resent standardized decisions when they conflict with their own occupational norms, particularly when their profession played no role in developing these standards (Sandholtz 2012). Professionals may also object to expending time and labor on conveying information to bureaucratic decision-makers in the standardized language those bureaucracies prefer—a phenomenon colloquially known as "red tape." Paperwork is especially likely to proliferate in the regulation of professional work, which is specialized and complex--and hence labor-intensive to convey into standardized language (*see* Timmermans and Berg 2003; Waring and Currie 2009; Sandholtz 2012).

Expert workers are particularly likely to experience regulation as burdensome when they are subjected to standards developed outside the profession (*see* Sandholtz 2012). This is the case with IRB regulation of qualitative research in social science and the humanities. Founded to monitor biomedical researchers within the U.S. Public Health Service (then the parent organization of the National Institute of Health), the IRB system was expanded in the 1960s and 70s in response to scandals in biomedical researchers, including the infamous Tuskegee Syphilis

study (Stark 2006: 27-71). Such scandals prompted the drafting of the Belmont report and of federal regulations that led to wider application of IRB rules. Both the regulations and the Belmont Report were developed with input primarily from researchers in biomedicine and psychology (Schrag 2010: 38-44).

In 1981, these regulations were revised (with input from non-experimental social scientists) to offer broad exemptions from IRB review to low-risk research, including research based on surveys, interviews, and observation (Schrag 2010: 42-53; 116). In the 1990s, however, in response to more biomedical scandals, federal regulators began to suggest that researchers were not competent to decide whether their own studies were exempt or not—rendering the concept of IRB exemption essentially meaningless (Katz 2007: 806). In a wave of enforcement activity, the Office of Human Research Protections (OHRP—the federal agency in charge of regulating IRBs, located under the Secretary of Health) suspended federal funding of research at eight major universities and hospitals (Schrag 2010: 133-4; Stark 2006: 16-17). Fearing federal sanctions, colleges and universities began to subject all research to the same IRB review process, even in cases where it was not federally funded—which was not technically required by the federal regulations (AAUP 2006).

In this way, sociologists—along with other scholars in the humanities and social sciences—came under the aegis of a regulatory system that had been honed over decades to regulate experimental research. Routines and scripts from biomedical research permeate this regulatory system, shaping local policies, procedures and decision-templates (Lederman 2006, 2007). Biomedical examples dominate the professional meetings, publications, and certification program of the professional administrators that increasingly run IRBs from behind the scenes (Schrag 2010: 139-40) However even faculty volunteers may find themselves adopting

biomedical templates in a field dominated by biomedically-oriented training programs (such as online courses), and where regulatory uncertainty creates an incentive to adopt established best practices.

Research Methods

To explore the role of standardization in qualitative researchers' experiences with IRB regulation, we conducted semi-structured interviews with 26 sociologists at nine institutions of higher education in the Northeastern United States. Because qualitative sociologists are clustered in geographically disparate units and under the jurisdiction of different IRBs, we used a multi-stage sampling approach. We started with a survey of sociology chairs in the Northeast of the United States to locate departments that were encountering more and fewer problems with their IRBs. We selected nine institutions to capture a range of reported IRB experiences—two more negative, three more positive, and three mixed. We then interviewed between two and four sociologists at each institution. Our nine institutions included four liberal arts colleges (10 respondents) and five research universities (16 respondents) (see Table 1).

[TABLE 1 ABOUT HERE]

All our informants were research active, and all reported having gone through IRB review at least once during the previous five years. Six of our respondents were either current or past IRB faculty volunteers, which allowed them to share valuable insights about the nature of the process. The first author of this article also served for three years on her institution's IRB.

Among the sociologists in our study, we found considerable variation—both in the attitudes they expressed toward their IRBs and the experiences that shaped these attitudes. Our respondents expressed a range of opinions regarding the legitimacy of IRB regulation of social

science. Two of our respondents believed that IRB review was both important and legitimate in its current form. One researcher and IRB volunteer explained her support for the process: "I think sociologists [underestimate] the amount of risk that people experience when they participate in their research…You need to set up these protections so that they don't get harmed by their participation" (Nora, Eastern College). In contrast, six of our respondents felt that IRB regulation of sociological research was antithetical to professional norms and illegitimate. In the words of Clara, at Rural College, "I'm sure when it comes to medical research or psychological experimentation IRBs are completely necessary; I don't think there is any role at all for fieldwork and participant observation."

However, the most common attitude among our respondents was a conflicted sense of regret that a system designed to attend to an important issue was causing problems. For example, one researcher initially stated: "I really think that IRB procedures are important because I think that a lot of people spend a lot of years doing things that I think are not ethical." Yet after describing a recent IRB decision that she viewed as mistaken, she backtracked: "I think that social and behavioral science researchers should really be undergoing very different kinds of checks than researchers who are doing medical research" (Penelope, Public University). Another remarked that "I think that IRBs can be productive and they can be really destructive and I think that … especially with social science research … the kind of research that is less science-y, they can really create a lot of problems" (Zaylie, Rural College).

The following two sections describe the experiences of these researchers with two varieties of standardization: standardized communication and standardized decision-templates. We then move to discussing our qualitative researchers' perceptions of the consequences of

standardization, and cross-institutional variations in the experiences of our researchers, and then conclude the paper.

Standardized Communication

Standardized communication, such as paperwork, allows remote regulators to monitor expert workers, translating information about complex activities and sorting it into simplified categories, allowing regulators to make a large volume of routinized decisions (Stinchcombe 1959; Timmermans and Berg 2003). However, control through standardization causes problems when it encounters work that is itself unpredictable and best governed by multiple, discretionary, ground-level decisions (Stinchcombe 1959; Leidner 1993). Such work is time-consuming to translate into regulatory language, and standardized communication may be particularly burdensome when the work is unique, unpredictable and difficult to routinize.

Michael, at State University remarked that "there's a lot of work to do to get the IRB to decide they're not all that interested in what you're up to." Completing an IRB protocol—an extended form describing a research project--can take a significant investment of time, even where the research is very low risk. However, the most common concerns about paperwork were related not to the burden of initial application, but rather to "serial reapplication"—that is to say, the submission of multiple versions of the same protocol before receiving approval. As one researcher put it, "they want a great deal of information on exactly what questions will be asked and procedures for maintaining confidentiality, and … they often then go back and ask for more information again" (George, Eastern University). Gabrielle, at State University, similarly recalled her experience:, "they'll send back a thing 'what about this, what about this, what about this' and now, you know, they can't possibly have a form that would imagine every possible

situation... [I]t took a good six to nine months of just trying to…come up with a protocol that would appease them."

We believe that the key to understanding the phenomenon of serial reapplication is that IRB decision-makers suffer from unusually high levels of uncertainty (Galbraith 1977). On the one hand, IRB decision-makers may be unfamiliar with the research site, topic, or methods, and therefore unable to evaluate risk without additional information. On the other hand, researchers may be uncertain about what their IRB requires and what information to include in an initial protocol. This double uncertainty is exacerbated by the ambiguous nature of IRBs' federal mandate, which leaves considerable room for local interpretation and discretion (Halpern 2007; Stark 2012). One faculty member remarked, the rules for getting through "weren't clear…You never had any idea what you would be caught on" (Sam, Yankee College). Marina recalled the experience of submitting a protocol at Public University: "I felt like the website was incredibly user-unfriendly … and then the process itself, they kept coming back to me with… problems that they felt were not addressed… And it wasn't really clear, you know, what I was supposed to do."

One way to clear up such mutual confusion between the regulated and their regulators is to develop standardized language and decision-templates or "boilerplates." In a field steeped in the norms and language of experimental biomedical research, templates appropriate to qualitative interview research may be lacking, and developing boilerplate protocol language could help clarify expectations on both sides (*see* Lederman 2007). However, qualitative research also has characteristics that make it relatively unamenable to this kind of routinization. Unlike most experimental or survey research, qualitative research involves a potentially infinite variety of research sites and participants. In reviewing qualitative research, IRB decision-makers face a series of complex, novel situations about which they must somehow estimate the likelihood and

magnitude of risk to participants. Standardized communication vehicles (i.e., forms) are simplified and streamlined by design, which means that it may take multiple iterations to convey all the necessary information about unique, non-routine situations. For example, Penelope, at Public University, recalled the example of a time-consuming series of reapplications involving a student proposal to study a social movement in a conflicted region in Turkey—a situation about which IRB decision-makers had neither knowledge nor appropriate precedents. As she concluded: "it's a group of people trying to think through the repercussions of something that they probably have less familiarity with than the researcher does."

The second recurring theme regarding standardized communication was the burden of filing amendments. IRB critics in the social sciences have argued that this burden is most acute for qualitative researchers, whose projects undergo multiple, iterative changes, whose research sites (e.g., street corners) are not under their control, and whose logic of inquiry is inductive (*see* Schrag 2010: 185; Lederman 2006: 484-5; O'Connor et al. 2008). Standard IRB procedures, which were developed with experimental, biomedical research in mind typically require researchers to spell out their research plans in great detail. Because even a minor change might, in theory, have ethical consequences, and because researchers cannot be allowed to make their own ethical decisions, IRBs typically require scholars to file formal amendments describing any changes and to wait for re-approval before resuming their research. One researcher asked if she could frame her research protocols more broadly so as to avoid the paperwork and delays resulting with resubmission: "They don't have any answer for me about what I should do, except 'well you have to submit an amendment'" (Gabrielle, State University). Alex at Private University, believed that other qualitative colleagues were often not filing amendments according to the letter of IRB rules: "there's a kind of belief that [IRB] essentially demands from

ethnographers that we wink at them to pretend that we're going to constrain ourselves to the questions that are pre-approved…And they in turn wink at us and give us permission to do the research as it's been scripted. And that system works, uh, so long as no one ever challenges anything that we do." At Riverside University, a qualitative researcher who also was serving as sociology graduate director, admitted that graduate students were not being encouraged to file amendments according to the letter of IRB rules: "when they do new things…We don't have a culture of asking them to file an amendment" (Christine, Riverside University).

Standardized Decisions

A problem commonly mentioned among our respondents was bureaucratic error—that IRBs made mistaken decisions based on a misunderstanding of the research. The kinds of decisions our respondents objected to almost never involved the outright prohibition of research; rather, they were routine modifications of research designs that rendered research difficult or unfeasible. Often, these modifications appeared to result from the application of decision-templates that functioned well for experimental research but poorly for qualitative research design.

There were several variations on this theme. One was the universal requirement of "site permission letters" from any institution where a researcher was recruiting subjects—a requirement that does not appear anywhere in the federal regulations, but that represents a sensible best practice for research at an institution responsible for the welfare of its population, such as a prison or hospital. This requirement could make it prohibitively difficult to do research that was likely to be critical of the permission-granting institution. For example, at Urban University, a graduate student studying an anti-administration student social movement at

another university was told he needed permission from that university's administration. Barbara, the student's advisor, remarked that "if the people studying the labor movement had to get permission from the factory owners, then nobody would have ever studied the labor movement!" Another example was the universal requirement of de-identifying informants--even in journalistic-style research where informants agreed to be quoted and where the credibility of the research rested on the attribution of quotes to well-known public figures. Still another example was snowball sampling: two researchers from Eastern University reported that their IRB had prohibited such sampling and suggested instead recruitment techniques commonly used in biomedical research, such as posting flyers in public places.

However, one issue stood out markedly above the others: namely, the requirement that all researchers acquire a signed consent form from each of their subjects. Such forms are not universally required in federal regulations, but they have often been interpreted by IRBs as the default norm (National Research Council 2014: 68-9). Going through an informed consent document outlining the risks and benefits of a study fits relatively well into the routine of clinical trials or surveys, in which the investigator controls the research process. However, it may fit poorly into the qualitative research process, where the investigator generally lacks such control (*see* Lederman 2006, 2007; Bradburd 2006; Fassin 2006; Taylor and Patterson 2010; AAUP 2012).

Thirteen of our 26 researchers mentioned the requirement of signed informed consent forms as an issue they had encountered. For example, Clara from Rural College wanted to interview adult passers-by at a conference convention booth. Clara's IRB required that she obtain signed consent forms; however, she found that the consent document posed insurmountable obstacles. As she put it "…[y]ou're asking them for all this personal information…*and* you want

them to sign a form that says that they're giving permission for this interaction, and as soon as you pull out the form, they say, 'no I don't have time.'" George at Eastern University had seen the problems IRB informed consent requirements posed for graduate students engaging in participant observation: "they somehow expect that everything will come to a halt while the graduate students pull out a form and explain to people they're talking with what it means and get their approval." Consent forms were seen as particularly problematic when they were long, legalistic, and difficult to read, as several of our respondents complained.

Many respondents reported having the impression that IRBs made mistakes because they were misapplying decision-templates designed for very different kinds of research. This theme was echoed by ten of our respondents. As one put it, "The model doesn't work; I don't think they understand what our philosophy is, or what grounded theory is" (Marilyn, Eastern University). In some cases, respondents attributed problematic decisions to IRB faculty volunteers from the discipline of psychology, which they often saw as dominating review boards. As one researcher who had served on her institution's IRB put it, "sometimes I think [qualitative] research isn't fully understood, especially by a committee that's more oriented towards psychological studies where you're putting … someone's right hand in cold water and judging their facial response" (Zaylie, Rural College). Other respondents viewed professional staff as the root of the problem: "it just feels like, you know, the random power being exercised by bureaucrats…who don't really have any idea what the research process is" (Marina, Public University).

The misunderstandings that contributed to these issues could be difficult to resolve when IRBs relied heavily on standardized communication, and where there was no appeal mechanism for contesting apparently mistaken decisions. Nancy, who engaged in a protracted

communications with her IRB about their prohibition of snowball sampling, recalled that this experience had altered her views on IRB, which had previously been strongly supportive. "I felt like … it's a faculty board, if you work reasonably with IRBs...it's all possible…But…I came away feeling like this was completely unreasonable, and you know it's a time sucker. I feel like my colleagues that don't do this kind of work don't realize the energy that one has to put into an application -- like this is a workload issue, (laughing) you know?" (Nancy, Eastern University). One researcher, who was serving as an IRB faculty chair observed that "if [IRBs] don't "get it," they can make some really problematic decisions, and when you have no appeal…then that can be a really big problem" (Sam, Yankee College).

Responses to Problems with Standardization

When asked about the consequences of IRB regulation for sociological research, our respondents expressed a range of opinions. Two felt that the consequences were primarily positive and had helped prevent real ethical abuses in social research. Thirteen believed that the consequences were primarily negative. The remaining eleven respondents either refrained from speculating about these consequences or felt that the consequences were mixed.

Interestingly, researchers who emphasized IRBs positive role universally felt that the benefits derived from IRBs' capacity to educate researchers, rather than to force them to comply. As one scholar noted, "I think that it just makes you more careful and thoughtful around those issues…[That is] the most important function" (Sarah, Eastern College). Twelve of our respondents emphasized this educational function, as opposed to only two who emphasized the IRBs' disciplinary role. Indeed, our respondents rarely encountered IRBs' disciplinary powers: we were only able to identify one instance in which IRB sanctions were applied, and none of our

qualitative respondents reported ever being audited by their IRB. As Christine at Riverside University mused, "We have this huge disjuncture between what people say they're going to do and then theoretically what they could do…And so the sanctioning part…I've never heard of an example of that, I've never seen it in action, and so the sanctioning part for me is…hypothetical."

Faced with requirements that they saw as antithetical to professional norms, and in the absence of tangible sanctions, some qualitative researchers engaged in various forms of covert defiance of IRB rules (*see* White 2007; Schrag 2010: 180-1; Taylor and Patterson 2010). Although we did not ask specifically about evasion in our interviews, eleven respondents reported that they were aware of colleagues or students who were evading IRB rules. Six of our respondents—also all qualitative researchers—reported that they had either evaded IRB rules themselves or recommended that their students evade them. Clara from Rural College, for example, discovered that it was impossible to interview passers-by if she presented them with the lengthy informed consent form required by her IRB (see quote above). Upon finding that people were unwilling to talk to her as soon as she presented the form, she decided to dispense with it. As she put it, "I just decided that I could either do field research or I could work with the IRB, but I couldn't do both." George, who had mentored graduate students doing qualitative research that had encountered similar obstacles, felt that "graduate students really are faced … with a choice of … either conforming to these rules and … not being able to do participant observation the way it should be done, or ignoring the committee…" (George, Eastern University).

Rather than flouting problematic decisions, qualitative researchers could also pre-empt them by misrepresenting their research in IRB protocols. Researchers often learned to do this from experience. Amelia, at Private University, lamented that "in a really insidious way, it's teaching [graduate students] to *lie*. I mean, (laughs), the only way to get… research done is just

to lie to them about what you're doing…but their requirements are so out of sync again with what you need to do, especially with ethnographic students, that, um, it's kind of like 'don't ask, don't tell' policy." Similarly, Jennifer at Riverside University described how an ethnographer graduate student had been confronted with impracticable IRB requirements—and had thereby learned that she could not be candid in her protocols. "I think from very early in her career, [it] set up a relationship with the IRB where she feels like she has to learn how to sort of play them, or navigate the system instead of feeling like she can propose something and then follow it precisely as outlined." Knowing from experience that IRBs would put impracticable limitations on her project, Greta at Yankee College opted not to apply to IRB at all, with the rationalization that her research was based on "conversations" rather than "interviews." As described above, other qualitative researchers simply failed to inform their IRBs of changes to research designs to avoid the hassle of further paperwork and delays.

Deviance from the rules allowed qualitative scholars to do their research, usually without sanctions, but it could be costly to morale. For example, Marilyn at Eastern University, who expended considerable time and effort trying to persuade her IRB to allow her to conduct snowball sampling in a low-risk project, expressed her frustration, remarked cynically: "I know that there are lots of researchers who aren't doing what their IRBs tell them to do. My problem is that I'm trying to abide by the rules!" Alternatively several researchers reported that they had decided not to do specific projects in order to avoid the effort involved with adhering to IRB rules. One claimed that she had "sworn off of doing any human subjects research anymore… I've found the process so crazy-making that … I just don't want to deal with it anymore" (Gabrielle, State University).

Institutional Differences

Although there were common themes, there were also important variations among the experiences and attitudes of our qualitative researchers. One important source of variation appeared to be institutional differences: local standards played a major role in how well or poorly our respondents felt the IRB process was working for their research. This is unsurprising, given the well-documented variations across the IRB system (Stark 2012). One institution, Private University, stood out as unusually negative: qualitative researchers perceived it as rigid and unaccountable. The experiences of our qualitative researchers at Eastern College, Rural College, and Urban University were all comparatively positive, for reasons described below. At State University, Public University, Eastern University, and Riverside University, researchers reported mixed experiences. Yankee College was unique: researchers reported having very negative experiences in the past, but its IRB was currently undergoing a major overhaul that seemed likely to improve researcher experiences. Overall, IRBs appeared to generate more positive experiences for our qualitative researchers when they were less bureaucratic, less reliant on standardized communication, and more open to faculty input and feedback.

The liberal arts colleges IRBs our study tended to be less bureaucratic, less reliant on paperwork as a means of communication, and more open to faculty input. This made it easier to easily resolve or even preclude the usual kinds of problems. Several respondents from these institutions indicated they were aware that their local IRBs were easier to work with than those at research universities. In the words of Clara, a Rural College faculty member who had previously worked at a research university, "It depends on the institution… I'm at a small liberal arts college now, it's much more laid back, I mean there's no doubt." More bureaucratic university IRBs relied much more on standardized communication to gather information about

potential risks to subjects. A comparison of the IRB application forms available on different institutions' websites highlighted this starkly. The IRBs of Eastern College and Yankee College had applications that were 3 pages and 1 page long respectively, each averaging 750 words. In contrast, the applications at Private, Eastern, and State Universities ranged from 7 to 13 pages in length, and averaged over 4,000 words per application.[1]

Instead of attempting exhaustively to transmit information through standardized forms, our liberal arts college IRBs were usually more open to informal communication with researchers. For example, at Eastern College, the sociology faculty member who served on her IRB took pride in being available to talk informally to colleagues and students about their research proposals. "[T]here's a face…somebody that they can stop in the hallway. People stop me in the elevator and ask me questions. And it's fine! Because I feel that's part of what I'm supposed to do" (Nora, Eastern College). Sam, the sociologist who chaired the IRB at Yankee College, similarly noted that "rather than submitting an application, getting it evaluated and getting it sent back to in a sort of bureaucratic way, [they/we] try to have back and forth discussions about what…the researchers are doing."

Such informal conversations could help forestall and resolve misunderstandings about research in unfamiliar international settings. For example, a student proposed a project that involved interviewing environmental activists in China. As an IRB faculty volunteer at Rural College, Zaylie witnessed first-hand the anxieties the proposal generated on the board, which "had a very cursory but not very detailed understanding of what happens to protestors in China." Rather than asking for a series of time-consuming formal reapplications and revisions, the

[1] The Rural College and Public University IRBs had password-protected online application systems, and therefore were not included in our comparison.

committee wrote to the student's advisor, "who wrote back and weighed in on the relative risks…[of] the research…because that faculty member was able to give us kind of the firsthand knowledge about the risks that we didn't [have]" (Zaylie, Rural College). Significantly, in addition to their lengthy application forms, the IRBs at Private University and Eastern University both required supplementary forms for international research, in which researchers needed to describe any factors that might heighten risks to subjects. At either of these institutions, a student conducting research on environmental activists in China would have invested more time—perhaps far more time--in paperwork and formal communication to address their IRB's lack of context specific information.

Whereas scholars from liberal arts colleges experienced their IRBs as groups of named individuals with whom they could have back-and-forth conversations, our research university scholars often experienced their IRBs as faceless bureaucracies. These large-scale operations were administered by full-time university employees rather than faculty chairs, and their policies and procedures were mostly insulated from faculty input. At State University, qualitative researchers attempted on two separate occasions to ask for modifications to local policies and procedures. Michael, who was among the researchers who met with IRB staff, recalled that there "was no change in any formal procedure or protocol," and that they had subsequently appealed to the Vice President for Research, "who simply shrugged and said 'these are State University rules and that's the way it is.'" Gabrielle, who was leading a second reform initiative at the time of her interview, described the frustration of trying to convince faculty volunteers to challenge the authority of the administrators at the IRB meetings she attended: "it's really largely run by the two administrators…[T]he academics on the committee often defer to them [when they say] 'that's the way it has to be'… so there's no pushing back."

However, at Urban University, professional IRB administration appeared to be working relatively well for qualitative researchers. Urban's IRB was run by a dynamic administrator who was committed to meeting personally with all researchers before they submitted protocols and engaging in back-and-forth communication. The three Urban University researchers we interviewed all expressed appreciation for this administrator's style. Barbara described the administrator as an enormous improvement over the person who had proceeded her in the position: "prior to that it just felt a little bit more like a black box, you know the IRB has its own email address...now I know that when I send something to that address it's [the administrator's name]…before then, what happened at the other end [laughs] of that email address was much less clear." Because the administrator was open to personal communication, it was possible for the advisors of the student being asked to use a site permission letter (described above) to successfully explain why a site permission letter was neither appropriate nor in keeping with the norms of qualitative research, leading to the reversal of the administrator's previous decision.

Our liberal arts college IRBs were run directly by faculty volunteers and led by faculty chairs. This did not necessarily mean that things always went smoothly for qualitative researchers. For example, some college scholars complained that their boards were dominated by experimental psychologists who applied inappropriate standards based on the experimental research paradigm. At Yankee College, the IRB faculty chair from the sociology department chose to engage with her colleagues in a purely bureaucratic way, and was famous for generating needless paperwork and delays. Yet because their influence was unmediated by administrators, qualitative researchers had the opportunity (even if not always seized) to directly shape the standards to which they were being held. At Yankee College, the old IRB chair had recently been replaced by Sam, a qualitative sociologist who had assembled a new group of faculty IRB

volunteers to improve and clarify rules and procedures, and who made an effort to communicate with researchers directly rather than bureaucratically. At Rural College when a faculty chair from the Department of Psychology was replaced by a new chair from the Department of Religion, there was an opening for sociological researchers utilizing qualitative interviews to have some of their concerns addressed. Eddie, who participated in this initiative while serving on the IRB, described going "from a very formal procedure..to..a looser, more sensible procedure, which is more accommodating to the needs of sociologists and anthropologists." He remarked with pride that "if you go on the website, what you see is essentially the product of back and forth between myself and the last [IRB faculty] chair…he accepted a couple of my ideas and I'm much happier with what's on the website now than the way that it used to be" (Eddie, Rural College).

Conclusion

In this paper, we have explored the experiences of 26 qualitative sociologists at nine different institutions with their IRBs. In keeping with the impressions of many earlier observers (*see* Halpern 2007; Heimer and Petty 2010; Bradburd 2006; Fassin 2006; Lederman 2006, 2007) we found that standardization was a dominant theme in their experiences—in contrast to the experiences of biomedical researchers, who complain about IRBs' inconsistency. We have argued that this is because it is IRBs' bureaucratic features that pose the greatest challenge to qualitative research. We have identified two forms of bureaucratic standardization—standardized communication and standardized decision-templates—and argued that both caused friction between our qualitative research and their IRBs. We have suggested that these frictions arose partly because IRBs lacked qualitative research-appropriate language and decision-

templates (Lederman 2007). However, we have also suggested that because qualitative interview research is inherently unpredictable, difficult to routinize, and unamenable to description through standardized bureaucratic language, the development of qualitative "boilerplates" is only a partial solution: qualitative research fits poorly with the routines of bureaucratic control (Stinchcombe 1959). Qualitative researchers had better experiences where IRBs relied less on standardized communication, and where researchers could have more direct input into IRB standards, which could thereby be aligned with their occupational norms.

The experiences described in this paper have wider theoretical implications. In today's "audit society," once-autonomous expert workers are increasingly regulated and called to account (Power 1997). Such regulation, and the standardization it engenders, can be accepted by affected professionals, or met with cynicism and resistance. These findings resonate with those of Sandholtz (2012) in a study of two groups of engineers required by top management to comply with international design standards. One group had standards imposed by distant bureaucrats, as inflexible directives. These engineers were most likely to believe these standards to illegitimate and irrelevant, and to resist them. In contrast, a second group of engineers played a more active role in authoring local standards that both met international requirements and were consistent with occupational norms. Members of this group came mostly to believe in the standards, and to uphold them voluntarily (Sandholtz 2012). Our findings similarly suggest that when professionals are able to shape the standards to which they are held, they are more likely to embrace them.

It is important to note that this paper has focused *only* on issues generated by IRB standardization, and have set aside at least two other important issues likely to affect qualitative researchers. First, a number of observers have argued that IRBs are prone to overestimate risk in

social research (Bledsoe et al. 2007; Heimer and Petty 2010; White 2007). Such risk-overestimation may result from organizations' propensity to "buffer" in the face of uncertainty, as well as individuals' tendency to overestimate risk in unfamiliar situations (Thompson 1967; Halpern-Felsher et al. 2001; Slovic, Fischhoff and Lichtenstein 2001). Consequently, a biomedical protocol involving life-threatening but well-understood procedures (e.g., tracheal intubation) might generate a less risk-averse response than an unfamiliar qualitative interview protocol (e.g., interviewing cruise ship workers) involving much smaller and more unlikely risks (Pritchard 2011; National Research Council 2014: 49-53). A second important issue left unexplored here is IRB "mission creep"—that is to say, the well-known propensity of organizations to adopt new goals, often to conform to the preferences of powerful local or systemic actors (Michels1959 [1915]; Selznick 1949). Some critics in the social sciences have argued that IRBs provide a convenient tool for university administrations to censor research that might potentially embarrass the university or put it at legal risk (cf. Bledsoe et al. 2007; Katz 2007; White 2007; Gunsalus et al. 2007). This was mentioned repeatedly among our interviewees, seven of whom opined that IRBs were "all about lawsuits," but few had any evidence to support this assertion. Future researchers might explore this issue through open-ended interviews with university administrators and through an analysis of IRB-approved informed consent templates.

The variations we report here suggest that at some institutions, sociologists and other qualitative researchers might be able to push for the implementation of more amenable IRB policies and procedures. However, we have also seen that not all institutions are equally receptive. Overall, the opportunities for widespread local improvements depend considerably on how what happens to federal regulations. In July 2011, the U.S. Department of Health and

Human Services (HHS) proposed a set of revisions to the regulations governing the IRB system aimed at "reducing burden, delay, and ambiguity for investigators," and in September 2016 posted a "Notice of Proposed Rulemaking" that is likely to resemble changes that are ultimately adopted (United States Federal Register, 8/8/2015).

Can qualitative researchers expect their experiences with IRB standardization to improve under revised regulations? The notice occupies over 100 pages of fine print in the Federal Register, and is mostly directed toward biomedical research (i.e., treatment of biospecimens); researchers in the humanities and social sciences are struggling to make sense of the meaning of the meaning of this proposal (*see* American Anthropological Association 2016). We therefore conclude on a speculative note by noting two features of the proposal that suggest that experiences with standardization would not improve under the new regime. First, the revisions appear to make human subjects regulations more ambiguous and complex. Historical experience suggests that complexity and ambiguity lead local institutions to respond with more homogeneous local standards as insurance against institutional vulnerability (Schrag 2010). Second, the revisions seem likely to eliminate the option, available under current regulations, for institutions to apply federally-mandated IRB review procedures exclusively to federally funded research. This would, for the first time, make all research with human subjects subject to federal oversight, auditing, and potential sanctions (Cohen 2006). Heightened federal oversight, combined with increased complexity and ambiguity, could heighten local institutions' perception of risk, and push them toward greater rigidity. This would suggest a future in which qualitative researchers continue to struggle to harmonize their work with the procedural standards of institutional ethics review.

Tables:

Table 1: Study Participants and Institutions (pseudonyms)

Institution Pseudonyms	Type	Respondent Pseudonyms
Private University	Research university	Amelia Alex
Yankee College	Liberal arts college	Sam Prudence Greta
Eastern University	Research university	Nancy George Marilyn
Public University	Research university	Marina Penelope
Riverside University	Research university	Jennifer Ana Christine
State University	Research university	Jim Gabrielle Michael
Eastern College	Liberal arts college	Julie Nora Sarah Lyra
Rural College	Liberal arts college	Clara Eddie Zaylie
Urban University	Research university	Sharon Barbara Elba

References

American Anthropological Association. 2016. "AAA Comments on Notice of Proposed Rule Making for IRBs.", Retrieved 1/25, 2016 (http://ethics.aaanet.org/).

American Association of University Professors. 2006. "Research on Human Subjects: Academic Freedom and the Institutional Review Board." Retrieved January 23, 2010 (http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm).

------. 2012. "Regulation of Research on Human Subjects: Academic Freedom and the Institutional Review Board." Washington, D.C.: American Association of University Professors.

Baron, David P. and David Besanko. 1984. "Regulation, Asymmetric Information and Auditing." *RAND Journal of Economics* 15:447-70.

Bledsoe, Caroline H., Bruce Sherin, Adam G. Galinsky, Nathalia M. Headley, Carol A. Heimer, Erik Kjeldgaard, James Lindgren, Jon D. Miller, Michael E. Roloff and David H. Uttal. 2007. "Regulating creativity: Research and Survival in the IRB Iron Cage." *Northwestern University Law Review* 101(2):593-641.

Boyd, Elizabeth A. 1998. "Bureaucratic Authority in the Company of Equals: the Interactional Management of Medical Peer Review." *American Sociological Review* 63:200-224.

Bozeman, Barry and Paul Hirsch. 2005. "Science Ethics as a Bureaucratic Problem: IRBs, Rules, and Failures of Control.(Institutional Review Board)(Author Abstract)." *Policy Sciences,* 12/01, pp. 269(23).

Bradburd, Daniel. 2006. "Fuzzy Boundaries and Hard Rules: Unfunded Research and the IRB." *American Ethnologist,* 11/01, pp. 492(7).

Brunsson, Nils and Bengt Jacobsson. 2000. "The Contemporary Expansion of Standardization." Pp. 1-17 in *A World of Standards,* edited by Brunsson and Jacobsson. Oxford.

Cohen, Jeffrey. 2006. "Checking the Box (HRPP Blog).", Retrieved 1/26, 2016 (http://hrpp.blogspot.com/2006/02/checking-box.html).

De Vries, Raymond, Debra A. DeBruin and Andrew Goodgame. 2004. "Ethics review of social, behavioral, and economic research: Where should we go from here?" *Ethics & Behavior* 14(4):351-368.

Fassin, Didier. 2006. "The End of Ethnography as Collateral Damage of Ethical Regulation?" *American Ethnologist* 33(4):522-524.

Fitzgerald, Maureen H. 2004. "Punctuated Equilibrium, Moral Panics and the Ethics Review Process." *Journal of Academic Ethics* 2:315-338.

Friedson, Eliot. 1994. *Professionalism Reborn: Theory, Prophecy, and Policy.* Chicago: University of Chicago Press.

Gunsalus, C. K., Edward M. Bruner, Nicholas C. Burbules, Leon Dash, Matthew Finkin, Joseph P. Goldberg, William T. Greenough, Gregroy A. Miller, Michael G. Pratt, Masumi Iriye and Deb Aronson. 2007. "Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep"." *Qualitative Inquiry,* 07/01, pp. 617.

Haggerty, Kevin D. 2004. “Ethics Creep: Governing Social Science Research in the Name of Ethics.” *Qualitative Sociology* 27: 391-414.

Halpern, Sydney. 2007. “Hybrid Design, Systemic Rigidity: Institutional Dynamics in Human Research Oversight.” *Regulation and Governance* 2: 85-102.

Halpern-Felsher, Bonnie L., Susan G. Millstein, Jonathan M. Ellen, Nancy Adler, Jeanne Tschann and Michael Biehl. 2001. "The Role of Behavioral Experience in Judging Risks." *Health Psychology* 20:120-126.

Hamburger, Philip. 2007. "“Ingenious Arguments" Or a Serious Constitutional Problem? A Comment on Professor Epstein's Paper." *Northwestern University Law Review* 102:102-6.

Heimer, Carol A. and JuLeigh Petty. 2010. "Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research." *Annual Review of Law and Social Science 6*:601-626.

Irvine, Janice. 2012. "Can't Ask, Can't Tell: How Institutional Review Boards Keep Sex in the Closet." *Contexts* 11:28-33.

Johnson, Tara S. 2008. "Qualitative Research in Question: A Narrative of Disciplinary Power with/in the IRB.(Institutional Review Board)(Personal Account)." *Qualitative Inquiry,* 03/01, pp. 212(21).

Katz, Jack. 2007. "Toward a Natural History of Ethical Censorship." *Law & Society Review* 41(4):797-810.

Lederman, Rena. 2007. "Educate Your IRB: An Experiment in Cross-Disciplinary Communication." *Anthropology News* 48:33-34.

------. 2006. "The Perils of Working at Home: IRB "Mission Creep" as Context and Content for an Ethnography of Disciplinary Knowledges." *American Ethnologist,* 11/01, pp. 482(10).

Leidner, Robin. 1993. *Fast Food, Fast Talk: Service Labor and the Routinization of Everyday Life.* University of California Press.

March, James G., Herbert A. Simon and Harold S. Guetzkow. 1993. *Organizations.* 2nd ed. Cambridge, Mass., USA: Blackwell.

Michels, Robert. 1959. *Political Parties: a Sociological Study of the Oligarchical Tendencies of Modern Democracy.* New York: Dover Publications.

National Research Council. 2014. "Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences.":1-126.

Noordegraaf, Mirko and Willem Schinkel. 2011. "Professional Capital Contested: A Bourdieusian Analysis of Conflicts between Professionals and Managers." *Comparative Sociology* 10(1):97-125.

O'Connor, Mary K., F. E. Netting and M. L. Thomas. 2008. "Grounded theory: Managing the Challenge for Those Facing Institutional Review Board Oversight." *Qualitative Inquiry* 14(1):28-45.

Power, Michael. 1997. *The Audit Society: Rituals of Verification.* New York, NY and Oxford, UK: Oxford.

Pritchard, Ivor. 2011. "How Do IRB Members Make Decisions? A Review and Research Agenda." *Journal of Empirical Research on Human Research Ethics* 6:31-46.

Sandholtz, Kurt W. 2012. "Making Standards Stick: A Theory of Coupled Vs. Decoupled Compliance." *Organization Studies* 33:655-79.

Schrag, Zachary M. 2010. *Ethical Imperialism: Institutional Review Boards and the Social Sciences 1965-2009.* Baltimore, MD: Johns Hopkins University Press.

Schneider, Carl. 2015. *The censor's hand : the misregulation of human-subject research.* New York, NY: NYU Press.

Scott, James C. 1998. *Seeing Like a State: How Certain Schemes to Improve the Human Condition have Failed.* New Haven: Yale University Press.

Scott, W. Richard. "Managing Professional Work: Three Models of Control for Health Organizations." *Health Services Research* 17(3):213.

Selznick, Philip. 1949. *TVA and the Grass Roots: A Study in the Sociology of Formal Organization.* Berkeley: University of California Press.

Slovic, Paul, Baruch Fischhoff and Sarah Lichtenstein. 2001. "Facts and Fears: Understanding Perceived Risk." Pp. 137-153 in *The Perception of Risk*, edited by P. Slovic. London and Sterling, VA: Earthscan

Stark, Laura J. M. 2007. "Victims in our Own Minds? IRBs in Myth and Practice.(Institutional Review Boards)(Response to Article by Malcolm M. Feeley in this Issue, p. 757)." *Law & Society Review,* 12/01, pp. 777.

------. 2012. *Behind Closed Doors: IRBs and the Making of Ethical Research.* Chicago; London: The University of Chicago Press.

Stinchcombe, Arthur L. 1959. "Bureaucratic and Craft Administration of Production: A Comparative Study." *Administrative Science Quarterly* 4(2):168-187.

Stinchcombe, Arthur L. 1990. *Information and Organizations.* University of California Press.

Taylor, Judith and Matthew Patterson. 2010. “Autonomy and Compliance: How Qualitative Sociologists Respond to Institutional Ethical Oversight.” *Qualitative Sociology* 33: 161-83.

Thompson, James D. 1967. *Organizations in Action.* New York: McGraw Hill.

Timmermans, Stefan and Marc Berg. 2003. *The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health Care.* Philadelphia, PA: Temple University Press.

U.S. Department of Health and Human Services. 2011. "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." *Federal Register* 76(143):44512-44531.

Waring, Justin and Graeme Currie. 2009. "Managing Expert Knowledge: Organizational Challenges and Managerial Futures for the UK Medical Profession." *Organization Studies* 30(7):755-781.

Weber, Max. 1946. "Bureaucracy." Pp. 196-244 in *From Max Weber: Essays in Sociology*, edited by H. Gerth and C.W. Mills. New York: Oxford.

White, Ronald F. 2007. "Institutional Review Board Mission Creep: The Common Rule, Social Science, and the Nanny State." *Independent Review* 11(3):547.

Yates, JoAnee. 1989. *Control through Communication: The Rise of System in American Management.* Baltimore, MD: Johns Hopkins University Press.