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Introduction

Research Governance and Research Ethics

An effective system of ethical review of research involving human subjects is vital to the protection of research participants (World Health Organization, 2009). But, just how well do IRBs and researchers protect the interests of those volunteering for research? Has the scope of an ever-expanding bureaucracy transformed ethics review into a component of research governance (Iphofen, 2009) protecting IRBs and institutions themselves from harm? Has this bureaucracy usurped or disempowered the role of researchers as planners of ethically responsible research? What accounts for this unaccountable bureaucracy? Haggerty (2004) and Ozdemir (2009) liken the growth of research governance to mission creep that attempts to serve two masters.

The first master protects research participants, and the second master protects the institution. Over time, however, the second imperative has sometimes mastered the former. Iphofen's (2009, p. 114) distinction between research governance and research ethics is useful to understanding how IRB mission creep and its oversight by federal regulators have become a problem for researchers. Gunsalus, Bruner, Burbules, Dash, Finkin, and colleagues (2006, p. 1441; see also de Jong, van Zwieten, & Willems, 2012) claim that the oversight of IRBs has become more about detail than substance.

Poor or missing 'Standard Operating Procedures' and "poor minute-keeping" account for about half of all U.S. Food and Drug Administration

citations, and quorum failures for another 13%, according to one review. In seeking compliance, universities have multiplied the number of IRBs, depleting the supply of willing and competent faculty. All this has generated a trend in which researchers increasingly think of IRBs as the “ethics police.”

As a result, research communities have reached an impasse. “Social scientists are angry and frustrated. . . . Their work is being constrained and distorted by regulators of ethical practice who do not necessarily understand social science research” (Israel & Hay, 2006, p. 1). Others complain of the homogenization of social research methods (van den Hoonaard, 2011), ethical imperialism (Schrag, 2010), epistemological bias (Bosk & DeVries, 2004; Punch, 1994; Tolich & Fitzgerald, 2006), inconsistency (Angell, Jackson, Ashcroft, Bryman, Windridge, et al., 2007; Kotecha, Lambert-Lanning, Keshavjee, Drummond, Godwin, et al., 2011; Pritchard, 2011; Stark, Tyson, & Hibberd, 2010; Upshur, 2011; Vulcano, 2012; Wiederhold, 2011), delaying research (Ceci & Bruck, 2009; Whitney, Alcsér, Schneider, et al., 2008; Wolzt, Druml, Leitner, & Singer, 2009), curtailing academic freedom (Taylor & Patterson, 2010; Weisse, 2009), the over-regulation of minimal-risk research (Ananth & Scheessele, 2012), and a lack of expertise (DeVries & Forsberg, 2002). These qualities of IRBs subvert their ability to safeguard human subjects from risk (Emanuel & Menikoff, 2011; Graffigna et al., 2010; Gunsalus et al., 2006; Haggerty, 2004; Hamburger, 2004; MacFarlane, 2008).

For IRBs to be useful to researchers and the people they protect, they need to recognize the regulatory and legal *box* within which they may be expected to operate and work creatively to overcome the limitations this box places on their effectiveness. Some elements of that box are as follows:

- Research governance may prioritize the protection of host institutions from litigation above actually protecting human subjects.
- The regulations governing IRBs are based on a medical model of human research in which one observes or experiments on some medical phenomenon as opposed to socio-behavioral research in which one interacts socially (e.g., by interviewing) or behaviorally (by inducing or observing how people act under specified circumstances).
- IRB review may be idiosyncratic, with decisions differing from one IRB to the next.
- IRBs thus may act as bureaucracies that do not offer researchers the right to appeal (Lantos, 2009).
- The IRB’s formal review of a researcher’s ethics application—what Guillemin and Gillam (2004) *term procedural ethics*—is partial, limited to an informed best guess, a snapshot of the ethical issues the researcher and the IRB expect to find in the field. This snapshot review does not and

cannot address ethical dilemmas or *ethics in practice* (Guillemin & Gillam, 2004), unanticipated problems that arise spontaneously in the field. IRBs are not present and are rarely helpful with problems of ethics in practice that traverse the entire research project from design through data collection and analysis to publication.

Almost all research conducted in the USA takes place within institutions of some kind—universities and colleges, businesses, nonprofit organizations, or governmental agencies. This has implications that the student of research ethics needs to understand. Your institution is legally and morally responsible for the treatment of human subjects within its domain; hence, it has reason to be concerned about the ethics of your research. You are deemed a risk, and the institution has established various methods of research governance to ensure that you perform ethically. Your institution is entitled to use those methods, which include IRB approval and oversight as it controls the purse strings on your project and even your very employment status within the institution. Here is how it works.

GRANTS AND CONTRACTS

We hear that Dr. So-and-so has received a grant. In most instances, however, the grant is not to Dr. So-and-so, although he wrote the proposal and will do the proposed work. The grant is typically to Dr. So-and-so's institution. A research proposal from a university is signed by many of the institution's higher authorities, typically including its president, provost, vice president for business, vice president for research, IRB chair, research foundation head, and Dr. So-and-so's dean and chair, among others. All of these people certify that certain standards will be met. Of special concern to the funder are standards of ethical treatment of human subjects and standards of fiscal responsibility.

Thus, Dr. So-and-so is hardly a lone researcher who devises his own standards of conduct. He has many authority figures breathing down his neck—and for good reason. Those authority figures, and the corporation that we call the institution, are legally required to enforce the standards to which they have agreed when they accepted the funder's money. If all this sounds like too much bureaucracy, dear reader, please ponder the following question: If you were the funder of a private research-granting foundation or the official in charge of a public foundation, would you be willing to mail a check for, say, \$300,000 to Dr. So-and-so, whom you have never met? Would you not prefer that an institution be responsible for overseeing Dr. So-and-so, who might be an irresponsible flake? The institution, after all, has much more control over Dr. So-and-so than does the funder.

PUBLIC RELATIONS

The institution in which the research is performed, even when the research is not funded and is simply your own one-person project, is still identified with your research, particularly if something goes awry and the newspapers headline the harmful things your project did within the community. Thus, your institution has arranged to hold you responsible for the ethics of any research you do. Even if you do your research in your home office, perhaps on your own computer, the research will still be identified with your institution. (You will show your institutional affiliation in the publication of your work, won't you?) Your contract of employment with your institution probably specifies, as part of the terms of your employment, that you will abide by and are governed by certain requirements of ethical conduct. Everyone, from your colleagues and department chair to your promotion committee and your institution's legal counsel, could bring pressure to bear to ensure that your research is conducted ethically.

MEDIA RELATIONS

A related aspect of research governance is that your institution is, in various ways, the owner of the research and is accountable to the media for what is done. Through its various means of research governance, the administration of the institution has at its figurative fingertips the rationale for undertaking the research, the methods that will be employed to protect human subjects, and the instruments of fiscal responsibility. Institutions are often called upon to explain why they sponsored or permitted research that has proven sensitive to public opinion. Your institution needs to be able to give a cogent and responsible explanation.

DEEP POCKETS

Your institution has additional reasons to supervise the research done by its faculty, staff, and students. And, these researchers have additional reasons to ensure that they operate under the requirements that the institution has set forth. In connection with any real or merely alleged harm that you may do to others through your research, you may be sued. Typically, institutions agree that, if their researchers operate within the institution's requirements (e.g., if researchers develop honest research protocols that are approved by the IRB and then follow the procedures they set forth in that protocol), the institution will defend them in any lawsuit. Of course, it is not just the researcher who is likely to be sued in such a case. The institution has far deeper pockets and might be sued for huge amounts of money. Thus, the researcher and the institution have a

mutual interest in working together to prevent even the appearance of wrongdoing or harm because lawsuits are expensive and emotionally costly events. This leads to what are often regarded as infringements on academic freedom, when a researcher undertakes to study something that the community may find offensive. Institutions typically feel strong pressure to respect academic freedom and walk a fine line.

CONFLICT OF INTEREST

In today's modern scientific and technological society, many researchers develop good ideas into lucrative consulting or other kinds of business activities. They may involve their students in ways that are very beneficial to the students and may support them financially through such work. However, it is also possible that such activities will conflict with the researcher's obligation to teach and to give students a wide spectrum of possible research opportunities. Recognizing that faculty research businesses may be both beneficial and harmful, most institutional governance of such work is conducted with sensitivity. Typically, researchers are required to declare any such activities, and the institution establishes ways of managing the potential conflict of interest so that its benefits can be realized without its harms.

HOW ETHICS WENT ASKEW

At the heart of institutional governance of research is the possibility of harm due to the research, the need for a shared understanding of the rationale for the research, and the need for institutional procedures to minimize risk. A closely related matter is the institution's responsibility to society at large. As we shall see, these three notions—minimization of risk, rationale for the research, and responsibility to society at large—are major themes throughout any discussion of research ethics. Yet, institutional governance is *askew* when the institution does more to protect itself from harm than to protect the research subject. As Gunsalus and colleagues (2006, p. 1441) have stated, mission creep has become counterproductive for the protection of those "others" who volunteer to participate in research.

Ironically, this obsession with paperwork and mechanical monitoring may undermine protection of human subjects. IRB members spend too much time editing documents, marking typos, and asking for more details . . . out of concern that one case in a thousand could slip through and generate bad publicity or penalties, or potentially shut down research. The result is that many protocols receive exaggerated review and the paper piles up. Society loses, as potentially productive research is discouraged or self-censored.

6 PLANNING ETHICALLY RESPONSIBLE RESEARCH

Mission creep is a central concern of any researcher planning ethically responsible research. So too is the backlash reaction to the failures of mission creep (Koski, 2010, p. 38):

Many pages in our literature on research ethics, policy and law, (provides) evidence of contemporary backlash among the scientific community in reaction to a failed regulatory scheme that, while with good intention seeks to promote ethical conduct of human research, has become viewed as an impediment to research progress. . . . The community of science today is expressing a collective sense of frustration, sometimes rising to the level of anger, with the existing approach to the application of research ethics to the conduct of human research.

The ascendancy of research governance means that many IRBs make institutional risk aversion their primary goal and research ethics (the protection of research subjects) a secondary goal. Hammersley (2009) goes as far as arguing that increased regulation by IRBs has not raised the “ethical standard” of social science, but more likely, it has worsened the quality of what social science produces.

Attempts to find a national solution to ethical imperialism or mission creep (Havard & Magnus, 2011) will continue to be well subscribed, but this quest is based on the assumption that North American IRBs all sing from the same songbook. Empirical evidence (Abbott & Grady, 2011) suggests the contrary. Thus, any solution to produce top-down reform of IRBs assumes that their behavior is predictable when evidence suggests that IRBs behave idiosyncratically.

Why?

To understand some reasons for this strange state of affairs, one must move one level up the hierarchy and examine the relationship between IRBs and the federal agencies that govern them. Klitzman (2012) interviewed IRB chairs and found that “IRBs are caught in the middle, and face considerable challenges, having to translate, implement, monitor and enforce these federal dictates with regard to specific local PIs and protocols” (p. 53). One IRB chair he interviewed said:

A lot of the regs don't make sense for scientists in the trenches. Policies sound nice, and I'd agree with them, but how do you implement and operationalize them—where you say, “I understand the spirit, but how do we get the spirit from this cut-and-dried yes-or-no kind of rule? (p. 53)

While one might hope that federal agencies would provide more guidance, that too can be a source of ambiguity rather than clarification. One respondent commented:

Every few months, OHRP and other agencies put out new guidance, and IRBs are jumping around to modify things to fit. There's not a lot of give and take

in terms of: is this reasonable, or helping? It's just mandated. We spent a lot of time reacting, changing things. That's not good. (Klitzman, 2012, p. 53)

Understaffed federal agencies are slow to respond to requests for clarification, and when they do respond, they may not give the kind of answer one seeks. One IRB chair commented:

Many times when you call for advice, they essentially just read back the regulations, and you basically have to make your own decision, which is great until you have an audit and you're told you didn't make the right decision. (Klitzman, 2012, p. 53)

As we will argue subsequently, there are many ways in which researchers and IRBs can work together to plan ethically responsible research. However, researchers should also respect the plight of the IRB, which sometimes operates between a rock and a hard place.

IDIOSYNCRATIC INSTITUTIONAL REVIEW BOARDS

Abbott and Grady (2011) provide the first-ever, systematic examination of how U.S. IRBs make decisions. Abbott and Grady (2011) reviewed 43 empirical studies focusing on IRBs' structure, process, outcomes, effectiveness, and variation. The 43 existing studies showed evidence of variation in multicenter review, inconsistent or ambiguous interpretation of the federal regulations, and inefficiencies in review.

In recent years, investigators and others have expressed dissatisfaction with the IRB system, criticizing it as dysfunctional (Fost & Levine, 2007), overburdened (Burman, Reves, Cohn, & Schooley, 2001; Office of the Inspector General, 1998) and overreaching (Gunsalus et al., 2006). Clinical investigators complain that the IRB review process is inefficient, and delays their research for what seem like minor modifications (Whitney et al., 2008). Research sponsors object that IRB review is time consuming, leading to delays that can significantly increase the costs of research. The public hears about problems and hence fears that research might be unsafe and existing protections ineffective (Lemonick, Goldstein, & Park, 2002). The current IRB system has also been described as out-dated and inappropriate for the scope and type of research being conducted in the 21st century (Maschke, 2008). Proposals to reform and improve the IRB system abound, including proposals to centralize, regionalize, or consolidate IRBs, strengthen and demystify federal oversight, infuse more support

and resources into the system, augment IRB member training, require credentialing of IRB professionals, mandate independent accreditation, educate the public, and continue to investigate “alternative” models of review (Institute of Medicine, 2002; National Institutes of Health, 2006; Steinbrook, 2002). (Abbott & Grady, 2011, p. 3)

A noteworthy finding by Abbott and Grady (2011) was that none of these 43 studies sought to determine how effective IRBs are at protecting human research participants.

Our task here is not to determine where ethics review went wrong but to help researchers navigate these often less-than-hospitable waters and offer some suggestions to IRBs.

As critics of the current IRB system, we are mindful of and respectful toward the overworked and under-thanked people who staff IRBs (Bosk & DeVries, 2004; Hardacre, 2012; Price, 2011); moreover, we recognize the processes of regulation as the problem, not the practice of ethics itself (Koski, 2010). Overregulation robs researchers of a sense of autonomy in how they practice ethics, potentially resulting in alienating researchers from their planning of ethically responsible research (Gunsulas et al., 2006).

We suggest essential changes of focus. Ethically responsible researchers must realize that IRBs are not the only site of ethics review. Researchers must not only be allowed to assume more responsibility, they must take full responsibility. Ethically responsible IRBs must realize that they are but one site of ethics review on a continuum. IRB approval of a research project does not guarantee ethical research. Consequently, researchers must be mindful of their ethical responsibilities throughout the life of the project.

Planning ethically responsible research means planning far beyond the beginning of a research project, meaning the informed consent stage. Responsibility for ethics is situated throughout the research process, the analysis, publication, and dissemination, including data archiving and sharing. It does not reside solely in formal ethical approval or, to use Guillemin and Gillam’s (2004, p. 1441) term, *procedural ethics*.

All researchers must take primary responsibility for professional, ethical conduct. Our systems should reinforce that, not work against or substitute for it; the IRB should be a resource, not the source, for ethical wisdom. All compliance systems require the buy-in and collaboration of the regulated, and it will be a sad day if scholars come to see human protection in research as the source of frustrating delays and expensive paperwork.

Why are we focusing on the relationship between the researcher and the people who volunteer to participate in research as if there were no ethics committee? In much social and behavioral research, there is always the potential for research

participants to transform a research problem that had been previously approved by an ethics committee. When this happens, and it does frequently, the researcher needs new guidelines to re-chart the new research problem. This assumes that researchers want to be ethical, and with the right guidance, this can be achieved at all stages of the research project, without an IRB (Blee & Currier, 2011).

A second limitation of the role of IRBs as the sole source of approval is the many sites of ethics review falling outside of the formal IRB approval process. Journal editors and their reviewers, funding agencies, the readers or consumers of research, students, the law, and of course, the research participants themselves participate in judging the ethics of research. Each has the ability to influence how ethically research is practiced. For example, before journal editors accept an article for publication, their reviewers evaluate the manuscript, typically including its ethical quality as well as its purely scientific quality.

Thus, IRBs are resources that provide opportunities for researchers to reflect upon and explain the ethics of their proposed research. Having to explain and justify one's research project to a dispassionate body is an ideal. Yet, within the ideal, there are many impediments.

NON-USA INSTITUTIONAL RESEARCH BOARDS

The IRB model is not universal. In Sweden and Denmark, for example, ethics review of social and behavioral research is not mandatory. In the mid-1990s, Denmark deemed ethical review of social science research unnecessary (Israel & Hay, 2006, p. 54). Bosk and DeVries (2004) cite the Netherlands, where social science research is exempt from review unless it places a demonstrable physical or psychological burden on its subjects. In New Zealand, ethics review is mandated only for health research and research conducted in the tertiary sector, and all government and nongovernment organization (NGO) research is exempt from IRB approval.

IN CONCLUSION

Since the publication of *Planning Ethically Responsible Research* in 1992, mission creep has engulfed researchers, their ethics, and their research. The way forward calls for a dual focus: first, the goal put forward in 1992 of “a logical ethical framework to guide investigators” needs to be updated to include new and revised methodologies, and second, the requirement that IRBs themselves engage in planning for their contribution to ethically responsible research should be put in place.

REFLECTIVE QUESTIONS

1. Why is research governance an important and legitimate role for institutions to undertake?
2. How has research governance come to be at odds with protecting human subjects?
3. In what ways can an IRB stimulate ethical problem solving by researchers?
4. In what ways can an IRB disempower researchers from their role as ethical problem solvers?
5. What do you think are effective ways to respond to this crisis in research ethics?