

“The Impact of Institutional Review Boards (IRBs) on Law & Society Researchers ”

Report of the Membership and Professional Issues Committee*
To the Board of Trustees of the
Law and Society Association
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I. Background

The history of IRBs is embedded in historical attempts to better ethically monitor biomedical research. Such attempts originated in the post-Nazi Germany Nuremberg Code in 1945, and later were more extensively formulated in the international ethical code of Declaration of Helsinki, which primarily focused on biomedical research. www.cirp.org/library/ethics/helsinki/.

Subsequently, IRBs in the USA were first established in the 1970s, growing out of regulations in 1953 that had been expanded in 1966 to cover all research funded by US Public Health Services. It is unclear whether IRBs in law and social sciences have any genealogical roots other than expansion of governmental monitoring in biomedical research into the social and behavioral science.

Pressures to establish IRBs in the US culminated following “public disclosure of the 30-year government subsidized Tuskegee Syphilis Study in which 300 black rural men were left untreated for diagnosed syphilis even after effective antibiotics became available” (University of Washington, History of IRBs, p. 2; www.washington.edu/research/hsd/irb_history.html). Hence, Public Law 93-348, National Research Act, was enacted in 1974, calling for the establishment of a national commission for the protection of subjects of biomedical and behavioral research www.ucop.edu/raohome/certs/93-348.html. There has been no mention, or expressed intention regarding human subject research in law and the social sciences, and clearly not all research in law and society is “behavioral”.

The purpose of the law has been to monitor research that involves some intrusion into the human body and/or its psyche. The original desire not to cover all fields of social sciences can be discerned from the **Belmont Report**, published in 1979 by the national commission. The report expressively and exclusively refers to biomedical and behavioral research. Paradoxically, however, it has resulted in the current sweeping Code of Federal

Regulations, Title 45-Part 46 Protection of Human Subjects, which was revised on June 23rd, 2005. www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101.

The original 1974 law and the constitutive documents did not mean to cover fields of expertise in which there is no direct intervention in the human body and mind. The Belmont Report states:

The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.

Strict readings of the constitutive documents have not necessarily justified the establishment of IRBs over law and society research. As such, the constitutional and ethical bases of IRB oversight in law and society fields are very debatable and unclear. On the other hand, the vague language of what is 'behavioral' research may provide IRBS with a rationale for scrutinizing studies in law and society that include personal interviews, use of archival sources, large scale surveys, expert surveys, observation, with no discretion. Indeed, the 2005 revised law does refer to interviews and surveys if the respondents can be identified. The current law states that IRBs will not cover

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- (i) *information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and*
- (ii) *any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation* (Code of Federal Regulations, 2005: Title 45-Part 46, section 46.101 B (2)).

The law has been expanded beyond the original intention that was articulated in the Belmont Report.

Moreover, the practices are even more intrusive than the law itself. For example, the current law excludes from IRB review the use of information open to the public, as well as interviews with formal authorities as long as the identities of these authorities remain confidential. In practice, current IRBs in universities cover those kinds of studies that use interviews with public authorities and knowledge accessible to the general public.

II. LSA Members' Input

At the request of MPIC, the Executive Office sent the following email to LSA Members on March 19, 2007:

Dear LSA Member,

The LSA Membership and Professional Issues Committee (MPIC) was asked by the LSA President to report about Institutional Review Boards' (IRBs') impact on the research of LSA members and/or their students. Please take a moment to send, by e-mailing Christine.Harrington@NYU.edu, brief details of any experiences with IRBs you would like us to be aware of while preparing our report. The details of your experiences may certainly remain confidential and will be used only for our informational purposes.

Thank you for your input,

Gad Barzilai
Bill Gallagher
Christine Harrington, chair
Virginia Mellema
Susan Olson

We received 24 responses within a two-week period. Those Members who responded mentioned the following 8 "impacts", listed here in no particular order:

1 2 3 4 5 6 7 8

Research delayed	Research rejected	Research changed to avoid	Excessive bureaucracy	Participants deterred	Political critique suppressed	Over-protective	Absurd requests
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Needless to say, the response rate was very low (See Chart 1, "Report", pp. 15-17). Several Members declined to put in writing their experiences or views, but offered to speak with a Committee Member. In these cases, MPIC did follow-up phone interviews.

We also contacted four Members who told us that they had in the past, or still were, serving on their universities' IRB. Since the names of faculty who review Human Subjects Research proposals are kept confidential, we made use of all opportunities we had to speak with Members who identified themselves as IRB reviewers. Three of the four faculty are social scientists while one is a law professor.

From these interviews, as well as our study of university websites (approx 15), we learned that the structure of IRBs varies from university to university and even within university systems where there are multiple campuses. Though this condition is noted frequently in the literature, MPIC found it useful to interview Members about the

relationship, if any, between the biomedical IRB research model and the social and behavioral IRB research model.

One question MPIC identified from the Member inquiry was whether the recent trend towards “empirical” research in law schools raised any issues relating to IRBs. Part of the impetus for this question stems from the fact that much legal scholarship is still primarily doctrinal, or philosophical in nature and, accordingly, does not generally concern human subjects. Law school-based empirical scholars, however, may potentially conduct research that includes human subjects.

In order to explore this further, one Committee Member investigated IRB procedures at his own institution, a regional law school at a small university in San Francisco. Both the law school and university have a formal policy relating to IRB requirements that mirrors general IRB procedures at many other universities. However, since both the university and law school are not primarily research-oriented, the formal IRB process is rarely used. For law faculty, the IRB process has been delegated to the Dean of the law school, who has the authority to review research for adherence to IRB guidelines or, more likely, to certify that research dealing with human subjects is exempt from IRB requirements under 45 CFR Sec. 46.101 (B) (exempt categories of research). The Committee Member’s own request for an exemption for his current research, involving semi-structured interviews with attorneys, is currently under review by the Dean of the law school.

Additionally, MPIC conducted a telephone interview with a faculty member at an independent regional urban law school who had previously identified himself by e-mail as having an opinion as to the use of IRBs. This faculty member, as it turns out, is currently one of the members of his law school’s IRB. He has recently reviewed requests for exemption from at least two law school faculty members conducting research involving survey data or interview data of human subjects. The requests were granted with little difficulty. This faculty member has strong opinions regarding the necessity of IRB procedures for most non-medical research. He also fears that overly strong IRB requirements threaten free speech of researchers, but he has no specific example of undue IRB interference in law faculty research at his institution.

MPIC also posted a request for information on IRB experience on the “Empirical Legal Studies” blog. This yielded only two e-mail messages from law school-based researchers, which were followed up by a Committee Member via e-mail. Both researchers indicated that they had worked with IRBs at their universities. There was no separate IRB for the law schools. Both researchers indicated that the IRB procedures were neither cumbersome nor problematic in their experiences, as both had recently submitted requests for exemption that were approved fairly quickly and uneventfully.

Finally, a member of the MPIC posted our query on one blog, the Empirical Legal Studies Blog and received two replies.¹

¹ One comment was posted to the blog and one sent directly by e-mail.
http://www.elsblog.org/the_empirical_legal_studi/2007/06/empirical_legal.html#comments.

MPIC found no special issues relating to IRBs and law school-based research, based on this very small number of examples. It may be that the types of “empirical” work that most law school-based researchers engage in is typically exempt under IRB guidelines.

III. Concerns about IRB “Over-reach”

A. Regulatory Avoidance: Altering Work to Avoid IRB

The literature on IRBs includes voluminous complaints about the difficulties of getting research approved. Some of these accounts include the strategy of changing one’s activities—in this case one’s research—to avoid or reduce contact with the IRB. For example, Schwartz-Shea and Yanow (2006: 26) note a collaborative study done by researchers at two universities who chose to conduct all of their human subjects research on students at the one university without a medical school because the other university’s IRB was judged to be easier to work with. Hamburger (2004: 348) cites several examples of professors changing class assignments or research topics to avoid IRB review. Historian Margaret Blanshard (2002) gave up studying the contemporary period and changed to the nineteenth century for this reason. She also cites a Duke University journalism professor who now limits class projects to “bland topics and archived records” rather than surveys on more controversial topics that students find more interesting but which require cumbersome IRB approval.

Psychologist Thomas Brinthaupt (2002) surveyed 23 full-time psychology professors from several institutions about both positive and negative effects of ethics reviews through IRBs. Respondents recognized some positive impacts, but “overall, faculty researchers reported that having to address ethical concerns had a generally negative effect on the development and conduct of research.” Brinthaupt reports one respondent who said s/he had “completely terminated the type of research I was drawn, trained, and would prefer to do. It changed the whole tone of what I do; sent me to survey and questionnaire work which substantially decreased my motivation to do research in general.”

B. Graduate Students & Junior Colleagues

UCLA sociologist Jack Katz suggests that changing research to avoid IRB review is especially likely among “less secure students and junior colleagues” (2002: as cited in Hamburger 2004: 344 n. 170), who are often under tighter time frames to complete research projects. Katz’s conclusion is supported by our own survey of LSA Members that produced three more examples of people changing research to avoid IRB problems. One undergraduate student’s public opinion survey question about reparations was flagged as “sensitive” and sent for full board review. Anticipating a couple of months’ delay, the student dropped the question to be able to finish the project in time. Another

undergraduate at a different university changed her thesis topic after revising the original project in response to IRB reactions and then having a second, different set of concerns raised after the resubmission, despite having conferred with IRB staff about responding correctly to the original concerns. From a third university a graduate student reported changing his dissertation topic after waiting several months without approval for a project that involved anonymous taping of speech in public locations.

Another aspect of regulatory avoidance is the number of scholars who manage to “fly below the radar” and do research that falls within the expanding IRB jurisdiction, but nonetheless do not submit request for IRB approval. Studies that attempt to estimate the amount of such non-compliance from ignorance or knowing choice are scarce, though Liddle and Brazelton (1996) conclude that psychology faculty who are dissatisfied with IRB policies and procedures are less likely to comply than those who are satisfied. This stance is probably only possible for faculty members doing unfunded research because other procedures required to process either externally or internally funded research create an opportunity to ensure that IRB rules are followed as well (Nelson 2003). Schwartz-Shea and Yanow (2006: 27) have noted disciplinary differences in the degree to which departments standardize training for PhD students on IRB procedures versus leaving this to individual supervisors, which suggests there could be disciplinary patterns in faculty compliance as well.

C. Consequences of Regulatory Avoidance

In order to reduce this type of non-compliance, Nelson (2003) predicts that “institutions are increasingly likely to commit themselves to campus-wide surveillance” via prepublication reviews. In one frequently cited instance at least, an IRB threatened to block publication when it happened to discover a nonfiction essay about to be published in a literary journal, which had not received IRB approval (Nelson). Nelson points out that from the perspective of IRBs, prepublication surveillance makes great sense, especially in the qualitative social sciences and humanities, because more of it is unfunded research and thus might have escaped scrutiny and because “the analysis and reporting of results are as likely as the research itself to produce significant interventions in people’s lives.” Nelson concludes: “[i]f the IRB chose to institutionalize prepublication reviews, it would need an immense staff and would produce a monstrous, intrusive surveillance culture that would substantively imperil academic freedom.”

D. Chilling Effect

A frequently expressed concern regarding IRBs is their potential for exerting a chilling effect on the research inquiries of junior scholars, particularly students. Linked to the problem of over-bureaucratization and its consequent delays, time-constrained graduate and undergraduate students may limit or abandon certain compelling research agendas in favor of less controversial projects that will gain more expeditious approval.²

² Eisenberg, et al. note that lack of timely, thorough and complete review is “detrimental to the productivity of an established researcher, but worse for a student gathering data for a thesis or dissertation or a junior faculty member who undergoes periodic evaluation” (Eisenberg, et al. 2004). A February 2007

Several of our respondents mentioned the difficulties of engaging in research that implicates the criminal justice system, a critical area of scholarship for the law and society community. For example, one University of California graduate student stated:

Our IRB . . . approved a limited version of my proposed study to interview the participants in California’s treatment and release of sex offenders. But they discouraged my attempts to gain entry into the correctional and mental health facilities which house sex offenders, requiring the approval of those facilities’ IRBs before [my campus] would grant approval. When I sought those facilities’ approval, they denied it until I could get [my campus’] approval! If I had another couple of years, I could probably work this out. But I don’t so I have given up . . . (Respondent 004).

A professor at an Ivy League University asserted that:

They [the IRB] have made it so difficult to do work at the juvenile prison that a tradition that has gone on successfully for years is probably ending this year. The student, who was trying to work there with his thesis this year, with approval of a Family Court judge and of the Training School principal, was not fully “approved” until March. He began the process in September (Respondent 014).

Another professor at a different Ivy League institution provided the comments of one of her students who was studying the impact of incarceration on women, particularly drug offenders:

I knew when completing my [questionnaire] that I would have some difficulty getting my topic approved because it related to a protected population. I completed the [questionnaire] honestly and accurately and finally heard back that I had to make substantial revisions to my proposal. Not only did I take all of the IRB’s recommendations for review into account when completing a second questionnaire, but I even had frequent contact with the compliance coordinator and the secretary to make sure I was doing everything correctly. I submitted a second [questionnaire] that covered all the areas that caused problems with my first proposal. Finally, I heard back, and I was rejected on a whole other set of criteria that IRB never mentioned when they rejected me the first time. Finally I ended up changing my topic enough so that I no longer had to deal with IRB because they had pushed back the start date of my research so far that I couldn’t risk not getting approved again (Respondent 019).

New York Times article, quoting a former member of an IRB at the University of Missouri at Columbia who studied review boards, stated “[T]he current process ‘obliterates a lot of research’ . . . because untenured faculty and graduate students on a timetable cannot afford to spend months waiting for approval. So, for example, ‘instead of talking to people who are victims of violence, you might look at newspaper articles. . . .’” (Cohen, 2007).

This is just a sampling of the feedback MPIC received with regard to IRBs' chilling effect on crime and criminal justice research. Other LSA Members' experiences included: (1) one campus IRB's general requirement that researchers not ask about illegal activity; (2) another university IRB's presumption that asking about investment decision-making would necessarily involve confessions to criminal activity, thus necessitating an intimidating written disclosure form which would scare off subjects; and (3) another IRB's refusal to approve a research protocol (after multiple revisions) involving interviews of domestic violence victims, necessitating the graduate student researcher's complete abandonment of the project.

However, this chilling effect is by no means limited to the criminal justice field and our impression is that it has well expanded into most or all fields of law and society inquiry. Other respondents mentioned that IRB designation of a particular population as "vulnerable," regardless of the specific nature of the research, can trigger extra-onerous requirements that restrict or even eliminate some research inquiries. These "vulnerable" populations can include such groups as members of the gay community and students (See section G below).

One of the most compelling anecdotes was from a professor advising two graduate students who are Turkish citizens who wanted to write dissertations on political prisons and honor killings in prison. She noted that the IRB representative imposed a requirement that the students secure approval from the Turkish government to conduct the research, a prerequisite that actually endangered the students. The professor likewise noted, "Given the vagaries of funding for graduate students, we often don't have the luxury of waiting for review processes to be complete in order to start field work" (Respondent xxx).

While no one can dispute the importance of assuring that research subjects and student researchers alike are not harmed and that undergraduate and graduate projects comply with ethical standards, there must also be recognition that important scholarship can be lost or compromised if students are subjected to unnecessary over-bureaucratization and inefficiency.

E. Data Destruction

An issue that has not received as much attention in the literature as those mentioned above, is the requirement of some IRBs that applicants provide detailed information on when and how they will destroy the data they collect (e.g., files, taped interview, photos, etc.). One person on MPIC became aware of this practice when she was asked, as the faculty supervisor for three graduate students, to sign off on their forms. Rather than question the requirement to data destruction, she found that students provided a data destruction scenario, as it were, that they did not intend to enact hoping that the IRB would not monitor.

Further investigation into data destruction requirement needs to be done. LSA Members we spoke to who are now, or have served on IRBs, had not seen this requirement imposed in their IRB process. They advised MPIC that this provision is an example of where the biomedical research model “slips into” or is simply “mapped onto” social and behavioral studies.

F. Consent Forms

MPIC was told by several LAS Members who served on IRBs that “people—faculty and students--- write protocol *way* out of proportion to what is asked for in numbers 2, 3, and often do not understand that public officials are totally exempt from the consent form provision . . . applicants completely over do it”. This same person we interviewed said that at his university approximately six out of ten basic social and behavioral research applicants are exempt from the consent form requirement under the Common Rules.

We were advised that “study information sheets” are what most social and behavioral researchers need to be in compliance with the Common Rules, not consent forms. Human subjects are then not forced to identify themselves by signing a consent form. A verbal consent to participate in research is what is most appropriate after the participant is given the “study information sheet.”

G. “Vulnerable” Populations

Some law and society research does involve what the Belmont Report calls “vulnerable, protected or targeted populations”. Studies conducted with persons who are incarcerated, children, people who have medical conditions, such as HIV-AIDS, are examples. A “full board review” will be triggered if the human subjects are in this category. While MPIC did not research on IRBs practices for this particular group, we have encountered disputes about whether Gay, Lesbian, Transgender and Bisexual person should or should not be deemed “targeted populations” (see section C above).

V. Recommendations

In general, MPIC suggests that rather than feed, or reproduce the IRB regulatory scheme that has already put into motion a “culture of fear” by adopting a formal-legalistic interpretation of the Common Rule, that the Association should take an active role with other professional organizations (i.e., COSSA, APSU, ASA, APA, AAA) to foster policy change at the national level.³ In addition, MPIC recommends that LSA develop a set of “best practices” for sociolegal research involving human subjects.

³ There is some evidence (see Schwartz-Shea and Yanow, 2006) that the US model is expanding to other countries. MPIC has not, however, looked into the issue of human subjects review at the international law.

A. National Policy

LSA should work with other professional associations at the national level to monitor the federal government and lobby for reasonable regulations that do not expand IRBs regulations.

1. Structure

- Emphasize that the biomedical, one-size-fits-all structure for IRBs is neither mandated by the regulations nor desirable. Studying the genealogy of the IRBs legislation shows that it was intended to regulate primarily biomedical research. Hence, the LSA should strive to minimize the scope of the IRBs regulations over non-behavioral studies and make the procedures of approving behavioral studies as smooth and expedient as possible.
- Oppose the “no-risk” logic that has led to policies, such as data destruction. While privacy of research subjects should be preserved where it is appropriate, destroying data is in complete contradiction to our training as scholars. The folklore that IRBs may be influencing researchers' notions about what *is* required should be addressed by academics. This is the “education” issue again. . An analogous problem arises in the area of “fair use” of copyrighted materials. For example, the accepted wisdom of what does/does not constitute protected fair use is often wrong and may drive teachers and universities to adopt policies and practices that overprotect copyright and undermine a vigorous fair use exception in an excess of caution and in the face of uncertainty as to what the law requires and allows.
- Oppose the centralized board system that can cause bottleneck delays and misapplication of the medical model to social science research. It appears that the most successful IRBs (in terms of "customer satisfaction") are those with a decentralized "sub-board" system. In contrast to the UC Berkeley system (which uses one Committee for the Protection of Human Subjects with a limited "exemption" process), UCLA and Macalester use a variety of "sub-boards" which review research projects based on the discipline, subject matter, population under study, etc. In addition to reducing delay and eliminating the one-size-fits-all problem, this decentralization allows for more subject matter expertise on the panel. This type of decentralization would work most successfully if graduate students and junior researchers are made familiar with the specific requirements, time deadlines, etc. of their particular sub-panels through some efficient means (sub-panel specific website, part of a research methods class lecture, etc.).

B. LSA

Generally, the more we generate discussion and education among LSA scholars, the more we may be able to influence a nuanced and contextual view of the IRB process, one that

moves away from hard and fast “rules” for most social science research, allowing for optimal protection of human subjects without inhibiting research goals.

- LSA should develop “best practices for human subject research on law and society” for Members to refer to as they prepare IRB applications and negotiate with local IRBs. LSA’s guidelines might begin with concrete “cases examples” solicited from sociolegal researchers. LSA should also draw on the expertise and experience of Members who have worked on IRBs and/or submitted applications. An example of ethical guidelines LSA might begin with is the UK’s Association of Social Anthropologists (2006) “ASA Ethical Guidelines: Ethical Guidelines for Good Research Practice”. Available online at <http://www.theasa.org>.
- Education of Members and the dissemination of LSA’s “best practices” should be done in coordination with MPIC and LSA-sponsored programs, such as the Annual and Regional Conferences, the Graduate Student Workshop, and the Summer Institute. This Report and subsequent guidelines should be posted on, the Association’s website, www.lawandsociety.org/.
- If our Members’ home departments, programs, centers and institutes should consider teaching their graduate and undergraduate students involved in human subjects research how to write “self-directing” protocols (e.g., study information sheets to give to human subjects and ask for a “verbal consent” where a “written consent waiver” has been obtained for “minimal risk, exempted research”).
- LSA should encourage continuing and systematic research on IRB practices through conference panels and publication. Such practices provide a classic example of legal regulation and sociolegal behavior in response. What topic could be more relevant for our association?

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