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Institutional Review Board Rules: Should One Size Fit All Disciplines?

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Synopsis

Almost every major United States university requires faculty members and students who wish to do research on “human subjects” to submit proposals to Institutional Review Boards (IRBs). These university Boards/committees, composed of faculty from various disciplines and a local community representative, have the authority to reject, modify or approve research proposals. If unapproved research is nevertheless conducted, IRBs can discipline the researcher and prevent publication. This authority extends to any research, funded or unfunded, that intends to create generalizable knowledge about humans.

The origin of the IRB system stemmed from moral outrage over abuses committed by some Nazi scientists and certain medical and psychological experiments that harmed subjects in the United States and elsewhere. The IRB rules were codified in the Belmont Report and adopted by the U.S. Department of Health and Human Services for federally funded research in the 1970s and 1980s. Since then other professional associations and most universities have also adopted them, regardless of the funding source.

IRB rules require researchers to treat all human subjects with “autonomy, beneficence and justice,” making no exception for those persons who have violated the legal or moral standards of society. The key to the process is fully informed consent of subjects which may make it impossible to obtain information from those who wish to hide conduct or opinions and thus can frustrate attempts to understand truths that may benefit the larger society.

Despite a consensus that universities should not permit research that risks harming vulnerable populations (children, mentally ill, prisoners, etc.), IRBs have created rules controlling research regarding the general population that far exceed legal proscriptions against libel and slander and are much more restrictive than any rules applying to non-university research. As a practical matter, the IRB process makes some kinds of research, which is otherwise frequently carried out by journalists or in think tanks, very difficult to do in academic settings.

IRBs have the power to censor both inquiry and publication. State sponsored or encouraged censorship is always controversial in American society and particularly so in universities. This paper will explore the legal and intellectual issues raised by the IRB rules and discuss their application to various disciplines (biomedical, behavioral, history, public policy, and journalism). It concludes that the IRB process and rules should be modified for most forms of public policy and journalistic research.

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I. Introduction and Methodology

In July 1972, the *Washington Star* published a story brought to it by a whistleblower about a U.S. Public Health Service clinical study conducted between 1932 and 1972 in Tuskegee, Alabama. The Tuskegee Syphilis Experiment observed the effects of that disease on largely untreated African-American males because the researchers wanted to study its undisturbed development.¹ Of the total 399 subjects who had acquired syphilis, some died of the disease or its complications and some passed it on to wives or children.

While the requirement to review medical research has existed since 1966, that newspaper story triggered an intense focus on the subject. In the spring of 1973, U. S. Senator Ted Kennedy chaired Committee on Health hearings on human experimentation where it was convincingly argued that there was insufficient review of experiments involving human subjects. The outcome of these hearings led to far stricter and more pervasive federal guidelines about the treatment of human research subjects and, eventually, Institutional Review Boards (IRBs) at all research institutions and universities that accept federal funding.

It is unlikely that any Senators foresaw that their actions would lead to a complicated academic and constitutional debate. The horrendous Tuskegee experiment, then and now, often stifles critical analysis of research review procedures. Nevertheless, IRBs have been accused of restricting academic freedom to do research and communicate about important issues in ways that are particularly inappropriate for social scientists and journalists. IRBs also have been criticized as a form of prior restraint or censorship that is inconsistent with American legal principles.

This paper, after describing the scope of IRB requirements, will set out some of the legal debates, but its principal focus is on the application of the IRB process to various forms of

¹ James H. Jones, *Bad Blood: the Tuskegee Syphilis Experiment*. (London: Collier Macmillan Publishers, 1981), 1.

disciplinary research. It will discuss whether the same set of rules should be applied to biomedical, behavioral, historical, anthropological, public policy and journalistic research. On one side are the societal and state desires to ensure that human subjects involved in federally funded research specifically and academic institutions generally are not mistreated. On the other side are the compelling interests of academic freedom and the dangers of censorship that undermines public access to truth about issues of public concern.

This paper is the beneficiary of the considerable amount of literature the IRB controversy has generated, particularly a new policy history, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009* by Zachery M. Schrag,² This article takes a different approach than existing literature by focusing on the question of the application of IRB rules to different disciplines. Our research is based on an extensive review of the debates within various disciplines, examination of federal regulations and court decisions, and on interviews with IRB administrators, constitutional experts, and other scholars.

II. The Scope of IRB authority

IRBs were certainly created with the best of motives. In 1974, The National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979, the Commission and the U. S Department of Health, Education, and Welfare, released the Belmont Report which laid out the general principles on which research policies would be based. Much of the inspiration for this report was the Nuremburg Code of 1947 and the Declaration of Helsinki, both of which concern ethical treatment and recruitment of the subjects of scientific and biomedical experiments.³

² Baltimore: Johns Hopkins Press, 2010.

³ Office for Human Research Protections, *OHRP 45 CFR part 46 Frequently Asked Questions (FAQs)*, Department of

The Declaration of Helsinki states that it is “the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.”⁴ The Belmont Report went further and covered both biomedical and behavioral research. Raising the specter of Nazi medical experiments as justification for federal oversight of medical and behavioral research, it stated:

Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners.⁵

The report called for strict informed consent procedures for all research subjects, and stated the three major ethical obligations of a researcher: respect for the autonomy of persons, beneficence, and justice. The respect for person’s obligation requires that research subjects either be treated as “autonomous agents” whose desires should be respected or as having diminished capacity and therefore meriting protection. The beneficence obligation commands that researchers attempt to “maximize possible benefits and minimize possible harms” to the research subjects. Researchers must also “do no harm” as it is “a fundamental principle of medical ethics.” The justice concept obliges the researcher to attempt not to unduly burden any person or vulnerable group of person for the sake of their research.⁶

The Federal Policy for the Protection of Human Subjects, known as the Common Rule,

Health and Human Services, <http://www.hhs.gov/ohrp/45CFRpt46faq.html>; see also, Office of Budget, Finance and Award Management, *Frequently Asked Questions and Vignettes: Interpreting the Common Rule for the Protection of Human Subjects for Behavioral and Social Science Research*, National Science Foundation, <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>.

⁴ World Medical Association Policy Publications, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, adopted 1964 and as adapted through 2008, World Medical Association, <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>.

⁵ National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Washington, D.C.: U.S. Government Printing Office, 1978. DHEW Publication No. (OS) 78-0012, 1978. Reprinted in *Federal Register* 44 (April 18, 1979): 23192.

⁶ *Ibid.*

was issued in 1991 and led to the creation of institutional IRBs. Currently, eighteen federal agencies or departments have signed onto this rule and enforce it within their respective jurisdictions. IRBs are currently regulated by the Office for Human Research Protections (OHRP), an office within the United States Department of Health and Human Services, which oversees enforcement of the Protection of Human Subjects regulations in the federal code.⁷

There are a few comparative studies of the actual operations of IRBs.⁸ At the University of Maryland Baltimore County (UMBC), a mid-size research university of about 13,000 undergraduate students, where one author teaches and the other author was an undergraduate, the IRB committee consists of ten members, all self-selected volunteers who often serve for many years. There is one community member who is usually someone known by other committee members, but who has no formal affiliation with the University. The committee meets every other month and processed 411 proposals in fy 2010.⁹ While it would be expected that in most cases the rules and the expectations of the researcher and the committee will be in congruence, in the official report of the committee, there is no record about how often the researcher and the committee disagreed. In such cases, there is usually an attempt to negotiate the differences. The staff director who works with the committee did not remember an instance where a proposal was permanently turned down, though sometimes the IRB required modifications.¹⁰ Should that occur, the researcher could appeal to the University Vice President for Research, but the federal guidelines do not permit anyone to

⁷ OHRP 45 CFR part 46 *Frequently Asked Questions (FAQs)*

⁸ An exception is Maureen Fitzgerald's research on 29 ethics committees in English-speaking countries as described at <http://institutionalreviewblog.com/2008/03/maureen-fitzgeralds-ethics-project.html>.

⁹ About 200 were new proposals, while the others were reviews of continuing research, proposed modifications or deviations.

¹⁰ Interview with Tim Sparklin, Administrator, Human and Animal Research Project, Office of Sponsored Programs, UMBC, July 6, 2010. Expedited reviews where risk is perceived to be minimal are made by two members of the committee. Reviewing the minutes of eight meetings, there were only two full committee votes, both unanimous.

overrule the IRB committee.

Obviously the UMBC committee and, presumably other IRB committees, handle their responsibilities carefully or there would be more of a sustained outcry against their operation. But it is hard to know exactly how they have affected research on the campus. What modifications have they insisted on? How often does that occur? Are decisions consistent from year to year, from funded to unfunded projects, from powerful departments to minor departments, from senior researchers to junior students? How many times do researchers, considering the real or perceived influence of an IRB review say to themselves, “Just don’t go there” and abort projects? The most effective system of censorship is always self-censorship.

While it is undeniable that the protection of human subjects was the noble goal of the Belmont Report and the initial regulations that come from it, there are credible arguments that the IRB system is operating as a massive nationwide board of censors which acts with little supervision, few records, and an unbalanced review process. IRBs have the power to “suspend or terminate” any research that, in the opinion of the IRB members, does not live up to the standards of the common rules. The only requirement imposed on the IRB, once this determination has been made, is to send the “investigator [and the] appropriate institutional officials... a statement of the reasons for the IRB's action.”¹¹

While there are a number of exceptions for certain kinds of “benign” research in the common rule, universities are discouraged from allowing researchers to independently decide whether their research is exempt.¹²

The normally exempted forms of research are as follows:

- Research in educational settings involving educational practices.

¹¹ 45 U.S.C. §46.113 (2009).

¹² *OHRP 45 CFR part 46 Frequently Asked Questions (FAQs)*.

- Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior, unless subjects are identified and disclosure of responses would involve more than reasonable risk.
- Research involving human subjects who are elected public officials.
- Research involving the collection or study of existing data if publicly available or unidentifiable.
- Research and demonstration projects designed to study public benefit or service programs.
- Taste and food quality evaluation and consumer acceptance studies.¹³

Most universities sign model assurance agreements removing exemptions, thus requiring all research in any way involving human beings must receive at least a cursory IRB review before it may proceed.¹⁴

IRBs are also expected to conduct cost-benefit analyses of the proposed research to consider the “anticipated benefits...to the subjects,” but also the “possible long-range effects of applying knowledge gained in the research.”¹⁵ This could be a problem if an IRB board has no member who is a specialist in the field of the proposed research. Consider the difficulty a board, consisting of specialists in medical ethics and the hard sciences, would have in rating the value of an oral history project that seeks to record interviews with military veterans or fishermen. The regulations attempt to address this problem by suggesting that IRBs invite other experts to be short term unofficial advisors to the board so that, “[a]ppropriate reviews for scientific merit must be conducted before the research is approved.”¹⁶

When considering the possible harm to the human subjects, IRB members are required to

¹³ NSF, “Frequently Asked Questions and Vignettes”

¹⁴ University of Akron Office of Research Services & Sponsored Programs, <http://www.uakron.edu/research/orssp/docs/IRBAppManualAug2007.doc>.

¹⁵ OHRP, Institutional Review Board Guidebook, Ch III, Part A.

¹⁶ *Ibid.*, Ch I, Part C.

consider possible psychological, social, and economic harms. These potentialities include “depression, confusion...feelings of stress, guilt, and loss of self-esteem.”¹⁷ The regulations go even further to warn that “Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence.”¹⁸ Obviously, when the topic is controversial, social scientists would have a difficult time showing that their research could not cause at least some of these reactions from some of the persons involved in the research. At the University of California Berkeley, the IRB chair announced that proposed research would be vetted not only for potential harm to individuals, but to groups and institutions because:

Even when research does not impinge upon it directly, a group may have been derogated or its reputation injured. Likewise, an institution, such as a church, a university, or a prison, must be guarded against derogation, for many people may be affiliated with, or employed by the institution, and pejorative information about it would injure their reputations and self esteem.¹⁹

Later, federal agencies said the regulations did not cover harm to groups, but that IRBs were free to consider the social policy implications of proposed research which on some campuses may open the door to a political correctness test.

Researchers themselves also are under scrutiny during the review process. Part of the cost-benefit analyses is an examination of the “qualifications of the principal investigator” to see if his or her “professional development”²⁰ is sufficient to take on the proposed project with a good chance that it will be completed successfully and without any harm to the human subjects. IRBs are advised that “[p]roposals that require skills beyond those held by the principal investigator should be modified to meet the investigator's skills, have additional qualified personnel added, or be

¹⁷ *Ibid.*, Ch III, Part A.

¹⁸ *Ibid.*

¹⁹ As quoted by Schrag, *op.cit.*, p. 45.

²⁰ *Ibid.*, Ch I, Part C.

disapproved.”

IRBs are bureaucratically independent from the rest of the university which they monitor. They are required to maintain detailed records, including meeting minutes, votes and attendance, but none of this information is available to the researchers.²¹ A researcher who was denied approval is entitled only to the simple explanation in the statement informing him of the denial. There is no appeal process that would provide checks and balances and he or she has no right to examine the record for further detail. The records exist merely so that the “authorized representatives of the department or agency supporting or conducting the research” may access them to make sure that the local IRB is properly enforcing the rules.²²

Membership of the IRB is also a point of contention. The boards must have a minimum of five members who must demonstrate diversity in “racial and cultural heritage, [and show] sensitivity to issues such as community attitudes.”²³ To do this, IRBs must include a member who is a “representative” of the “local community-at-large”. Good candidates should be “knowledgeable about the local community and be willing to discuss issues and research from that perspective,” and are preferably racially representative of the community.²⁴ For an institution such as New York University or the University of Chicago what person could be representative of the community at large? Such a role may add to a problem of potential censorship, however, because this representative is asked to represent local values. Obviously the moral standards of this individual could vary greatly depending on the location of the university. Imagine the difference between the community representatives at University of California, Los Angeles Berkeley and the University of Mississippi.

²¹ *Ibid.*, Ch I, Part B.

²² *Ibid.*

²³ *Ibid.*

²⁴ *Ibid.*, Ch. I, Part B.

OHRP has substantial powers to enforce the Common Rule. Before a university may receive federal funds, it must negotiate and agree to an assurance that its researchers will follow the Common Rule, the Belmont Report, and any other requirements that the university agrees to in the negotiation. Upon a finding that a university is not in compliance, OHRP has a number of options. It may suspend the assurance until certain requirements are met. It may require additional oversight or deny the use of the exemptions, even beyond the original assurance. Finally, OHRP may advise the Department of Health and Human Services to permanently end all federally funded research at the institution.²⁵

III. Legal Issues

Given the emphasis on freedom of speech and academic freedom in American law, the existence of IRBs in the fabric of university life is a paradox.²⁶ These powerful, unaccountable boards could become a form of suppression of unpopular research and ideas.

The Supreme Court articulated a vigorous defense of academic freedom in *Sweezy v. New Hampshire* (1957) declaring:

The essentiality of freedom in the community of American universities is almost self-evident. No one should underestimate the vital role in a democracy that is played by those who guide and train our youth. To impose any strait jacket upon the intellectual leaders in our colleges and universities would imperil the future of our Nation. No field of education is so thoroughly comprehended by man that new discoveries cannot yet be made. Particularly is that true in the social sciences, where few, if any, principles are accepted as absolutes. Scholarship cannot flourish in an atmosphere of suspicion and distrust. Teachers and students must always remain free to inquire, to study and to evaluate, to gain new maturity and understanding; otherwise, our civilization will stagnate and die.²⁷

²⁵ Ibid., Ch I, Part D.

²⁶ For a symposium on the legal issues presented by IRBs see the *Northwestern Law Review*, Vol.101, No. 2. For example, Phillip Hamburger, "Getting Permission," and Jerry Menikoff, "Where's the Law? Uncovering the Truth About IRBs and Censorship." See also Phillip Hamburger, "The New Censorship: Institutional Review Boards," *Public Law and Legal Theory Working Paper No. 95*, University of Chicago Law School, May 2005. <http://www.law.uchicago.edu/academics/publiclaw/index.html>

²⁷ *Sweezy v. New Hampshire*, 354 U.S. 234, 250 (1957). See also, *Keyishian et al v. Board of Regents of the*

The reference to freedom of inquiry and the social sciences seem particularly relevant to the controversy over IRBs.

Moreover, IRB review represents a form of prior restraint before publication which is the most damaging form of censorship. In *Bantam Books, Inc. v. Sullivan* (1963), the Supreme Court declared “Any system of prior restraints of expression comes to this Court bearing a heavy presumption against its constitutional validity.”²⁸

Nevertheless, despite the general frequency of litigation in the United States, there have been no major judicial decisions concerning IRBs. While courts have been very protective of academic freedom if the threat is external to the university, IRBs are internal university committees and courts have been deferential to campus decision making which seems based on academic values.²⁹ So the outcome of any future litigation might be heavily fact dependent. Was the campus being pressured by federal agencies to censor research? Was the research funded or unfunded?³⁰ Was the purported violation of ethics also inconsistent with professional ethical norms? Did the IRB decision seem ideological and not based on consistent rules?

The following sections examine where those lines might be drawn in various disciplines.

IV. Applications to Disciplinary Research

A. Biomedical Research

University of the State of New York et al. 385 U.S. 589, 603 (1967).

²⁸ *Bantam Books, Inc. v. Sullivan*, 372 U. S. 58, 70 (1963). See also *Near v. Minnesota*, 283 U.S. 697, 713 (1931).

²⁹ *Regents of the University of California v. Bakke*, 438 U.S. 265 (1978) and *Grutter v. Bollinger*, 539 U.S. 306 (2003).

³⁰ But see *South Dakota v. Dole*, 438 U.S. 203(1987), where the Court held that despite the general power of the federal government to attach conditions to its grants, the conditions can not require recipients to give up their constitutional rights.

In addition to the Nazi experiments and the Tuskegee Syphilis Study, there are other horror stories in biomedical research before IRBs were fully developed. In 1963, a medical researcher at the Jewish Chronic Disease Hospital injected live cancer cells into the blood stream of chronically ill patients who were suffering from dementia to study how their weakened immune systems would respond. From 1963 to 1966, researchers at Willowbrook, a state institute in New York for profoundly impaired children and adolescents, intentionally infected children with a mild strain of hepatitis. Some of the children allegedly were refused admission until their parents consented to their participation in the study, and the parents were only informed that their children would be vaccinated as part of the research.³¹ In “Ethics and Clinical Research,” Dr. Henry Beecher cited nineteen cases where human subjects were mistreated in medical research in the United States dating back to 1948.³²

In the biomedical field, there were also infamous post-IRB misbehaviors. In 1999, a research subject in an approved gene therapy trial at the University of Pennsylvania’s Gene Therapy Institute died after an adverse reaction to an injection. OHRP found a number of violations by the University’s local IRB, including a lack of continuing review of the project and a failure to describe all the foreseeable risks in the informed consent document.³³ A year later, OHRP suspended research at the University of Oklahoma Health Sciences Center for failing to properly safeguard the interests of terminally ill research subjects.³⁴ From 1998-99, OHRP suspended research at ten different universities and medical centers. In 2000, research

³¹ Harold Y. Vanderpool, “Introduction and Overview: Ethics, Historical Case Studies and the Research Enterprise”, in *Ethics in Research Involving Human Subjects: Facing the 21st Century*, ed. Harold Y. Vanderpool (Hagerstown, MD: University Publishing Group, 1996), 9-10.

³² Jon Harkness, Susan E. Lederer, and Daniel Wikler, “Laying Ethical Foundations for Clinical Research”, *Bulletin of the World Health Organization*, 2001, World Health Organization, <http://www.who.int/docstore/bulletin/pdf/2001/issue4/vol79.no.4.365-372.pdf>

³³ Danielle C. Beasley, “Coupling Responsibility With Liability: Why Institutional Review Board Liability Is Good Public Policy,” *Northern Kentucky Law Review* 36 (2009): 50-52.

³⁴ *Ibid.*

was at least limited at five different medical or academic institutions. In many of these cases a recurring problem was lack of sufficient continuing review.³⁵ Finally, in 2001, John Hopkins University School of Medicine's IRB was cited for insufficient continuing reviews which, in part, contributed to a subject's death, and for approving inadequate informed consent procedures.³⁶

There is less debate about the necessity of IRB reviews for biomedical research.³⁷ Gerald S. Schatz argues that the Belmont report was a necessary response to the abuses to research subjects in biomedical experiments.³⁸ He points out the particular vulnerability of some participants in biomedical research because many "are medically desperate; many are poor, illiterate or relatively uneducated; many lack effective access to medical care and to legal recourse."³⁹ Subjects in biomedical research may be far more likely to believe that the researchers are acting in their personal best interest, as their own doctor would do. This leads participants to be more trusting, and therefore more vulnerable. In social science and humanities research, participants may be far less likely to assume that the researcher is seeking to provide them with a personal benefit.

But Schatz also sees IRB review of social science research as part of the problem. He explains:

It's rare that social research gets much more invasive or threatening than what's asked in a routine family history during a routine medical examination....In the current regulatory climate many IRBs treat social and behavior research as if it were very risky. The focus on

³⁵ Sharona Hoffman, "Continued Concern: Human Subject Protection, The Institutional Review Board, and Continuing Review," *Tennessee Law Review* 68 (2000-2001): 727-728.

³⁶ *Ibid.*

³⁷ David Glenn, "Inside the Risky World of Drug-Trial 'Guinea Pigs,'" *The Chronicle of Higher Education*, July 16, 2010.

³⁸ Gerald S. Schatz, "Are the Rationale and Regulatory System For Protecting Human Subjects Of Biomedical And Behavioral Research Obsolete and Unworkable, or Ethically Important but Inconvenient and Inadequately Enforced?" *Journal of Contemporary Health Law and Policy* 20 (2003-2004): 26.

³⁹ Gerald S. Schatz, "Ethical Lawyering in the Protection Of Human Subjects Of Biomedical And Behavioral Research," *Michigan State University Journal of Medicine and Law* 13 (Winter 2009): 151.

very minor or unlikely risks has resulted in lengthy negotiations between IRBs and investigators and overly detailed, insultingly paternalistic, informed consent procedures.⁴⁰

Though necessary and well intended in these situations, IRBs are often overworked and unable to give sufficient attention to biomedical research. A General Accounting Office (GAO) report to the U.S. Senate found that many local IRB members were operating under a “heavy workload. “ In the report, OHRP officials admitted that, in some cases, the “IRB workload demands have reduced the quality [of] review,” with some IRBs reviewing up to 150 research proposals per session.⁴¹ If many of these proposals were from the social sciences or humanities research, it may be that the oversight of these proposals by IRBs has diluted the oversight of biomedical research. One possible solution, advocated by Dale Carpenter, would be to “establish separate IRBs for biomedical and social science research at all universities.” This would lessen the workload for reviewers on the biomedical IRB and would allow for more specialization on the social science IRB that would hopefully better facilitate review. The downside would, of course, be an increase in bureaucracy and expense.⁴²

B. Behavioral Research

Behavioral research as conducted by psychologists often crosses the border of medical and social science research. Sometimes, psychologists are dealing with patients, clients, or just fellow citizens. Different rules apply to different settings. Psychologists S.J. Ceci and M.

⁴⁰ Schatz, *op. cit.*, *Journal of Contemporary Health Law and Policy* 6-7.

⁴¹ General Accounting Office, *Scientific Research: Continued Vigilance Critical to Protecting Human Subjects*, Report No. HEHS-96-72 (Mar. 8, 1996), 17 -19.

⁴² Dale Carpenter, “Institutional Review Boards, Regulatory Incentives, and Some Modest Proposals for Reform,” *Northwestern University Law Review* 101(Special Issue, 2007). 701.

Bruck have suggested that there needs to be (1) a process for appeal of IRB authority and decisions; (2) systemic evaluation of the risks and benefits of IRBs; and (3) evaluation of the skills and competence of IRB members.⁴³ In 2010 the American Psychological Association formed a new committee to examine federal regulation of psychological research so there may be further clarification of these issues.

In the behavioral sciences, there are fewer stories of research of questionable ethics, but still there are enough examples that the Department of Health, Education, and Welfare thought it necessary to include behavioral research in the Belmont Report. Perhaps the most famous example are two Sixties studies: Stanley Milgram's infamous obedience experiment⁴⁴ and Laud Humphreys's study of male homosexuality.⁴⁵

But while both of these examples raise difficult questions, do they justify the need for blanket IRB oversight of behavioral research? Is the harm anywhere near the harm caused by mistreatment in biomedical research? An anecdote about one or two studies does not constitute systematic data.⁴⁶

According to Jack Katz,

[t]here is no historical evidence that the social science and humanistic research now pre-reviewed by IRBs ever harmed subjects significantly, much less in ways that could not be redressed through post hoc remedies. The optional decision to push all ethical review of social science and humanistic research through a prior review sieve is not only massively inefficient, it is also counterproductive where risks are most serious.⁴⁷

⁴³ S.J. Ceci and M. Bruck, "Do IRBs Pass the Minimal Harm Test," *Perspectives on Psychological Science*. DOI 10.1111/j.1745-6924.2009.01084.x,

⁴⁴ Stanley Milgram, "Behavioral Study of Obedience," *Journal of Abnormal Psychology* 67 (1963).

⁴⁵ Laud Humphreys. *Tearoom Trade: Impersonal Sex in Public Places* (New York: Aldine Publishing Company, 2005).

⁴⁶ John H. Mueller, "Ignorance is Neither Bliss nor Ethical," *Northwestern University Law Review* 101 (2007) 811.

⁴⁷ Jack Katz, "Toward A Natural History Of Ethical Censorship," *Law and Society Review* 41 (December 2007), 807.

On the other hand, one of the main supporters of IRBs, J. Michael Oakes, argues in his frequently cited article “Risks and Wrongs in Social Science Research,” that “the absence of data on risks and wrongs in social scientific research does not prove that subjects go unscathed.” As a consequence, he admits that “IRBs must speculate and make decisions on the basis of worst-case scenarios.”⁴⁸ But is the worst-case scenario, the proper standard for determining whether research can go forward?

We agree that those classes of persons designated as vulnerable (pregnant women, fetuses, and neonates, prisoners, children, individuals with otherwise diminished capacity) by OHRP should merit special protection. However, is it really necessary that all research involving human subjects receive prior approval and continuing review when there is so little evidence of harm, given the barriers to research, inconvenience, and time not spent protecting subjects that are truly vulnerable.?

While the legitimacy of IRB reviews regarding biomedical and some types of behavioral research is generally accepted, there is great controversy over the role of IRBs for social sciences and humanities studies. One of the most frequent criticisms is that IRB founding documents define the ethical relationship between doctor and a patient and that the regulations were written without consideration for the issues specific to other fields. Dean Gallant, the Director of the Committee on the Use of Human Subjects in Research at Harvard University, tried to clarify how the Common Rule should be applied to the social sciences for IRB members and had to concede:

Some regulatory guidance is available – but not much. Because the Common Rule focuses largely on quantitative procedures (experimental protocols, hypothesis testing, controlled studies) and primarily in the biomedical area, many aspects of the regulation are a poor fit for the circumstances of qualitative research. It is no surprise that IRBs struggle as they try to apply these regulations to ethnographic studies, focus groups, or

⁴⁸ Michael J. Oakes, “Risks and Wrongs in Social Science Research: An Evaluator’s Guide to the IRB,” *Evaluation Review*, (October 2002): 449.

oral histories.⁴⁹

C. History

History is a discipline that depends on precision in names and dates and often involves evaluation of the actions of particular individuals and institutions. Who would want to read a history of an unnamed “Eastern European war ” or a “Central American country”? The histories of the contemporary financial implosions are specific in recounting the misdeeds of AIG, Bear Stearns, and Lehman Brothers and their executives and those details are essential to their credibility.⁵⁰

To the extent that history can be written based on public documents, the IRB process is not very confining, though the idea that a committee rather than the scholar should decide how persons should be treated with benevolence and justice is worrisome.

More difficulties with IRBs occur when the oral history technique is used for direct interviews. A guide to human subjects research states;

Biography or oral history research involving a living individual that is not generalizable beyond that individual may not be considered human subject research. Researchers are advised to contact their local IRB as these subjects may be subject to local interpretation.⁵¹

Apart from the question of whether human subjects are more likely to be harmed by generalizable research than non-generalizable research, it would be a contextless and unsatisfying piece of historical research that made no generalized statements about the actions of the subject and other peers.

Oral Historians contend that their IRBs treat them as if they could use the same strict

⁴⁹ Robert J. Amdur and Elizabeth A. Bankert, *Institutional Review Board: Management and Function* (Sudbury, MA: Jones and Bartlett Publishers, 2002).

⁵⁰ Among the many examples is William D. Cohen, *House of Cards: A Tale of Hubris and Wretched Excess on Wall Street*, New York: Anchor Books, 2010.

⁵¹ Maristela Cho and Susan L. Rose, “Students in Research” Collaborative Institutional Training Initiative. downloaded 11/11/2009. <http://www.citiprogram.org/members/learners> II/moduletext.asp?

procedures that medical researchers use to control their experiments, and that when they are forced to remove identifying information from the records of their interviews a great deal of historical value is lost.⁵² The American Historical Association concluded:

[An] historian's deepest responsibility is to follow the evidence where it leads, to discern and make sense of the past in all its complexity; not to protect individuals from possible repercussions from past mistakes or misdeeds. In this we are akin to journalists and unlike medical professionals, who are enjoined to do no harm.⁵³

D. Anthropology and ethnography

Other social scientists have different problems. Some anthropologists and ethnographers⁵⁴ argue that IRB members do not have a real understanding of what ethnographers do and do not trust their methods.⁵⁵ Others contend that until IRBs recognize that sometimes the people they interact with in their research are not “human subjects” in the traditional sense of the word, there will be continuing friction.⁵⁶ Dr. Daniel A. Bradburd, a Professor of Anthropology at Clarkson University, argues that ethnographers go in and out of “research” when doing anthropology-style research. Since ethnographers draw conclusions from simple interactions, just meeting and talking to new people can be considered research. IRB rules assume that there are specific places and planned times for research to occur to create informed consent – but it just does not work that way with

⁵² American Historical Association, “AHA Statement on IRBs and Oral History Research., *Perspectives on History*, 2008, available online via <http://www.historians.org/perspectives/issues/2008/0802/0802aha1.cfm>.

The Canadian rules on oral history regarding persons involved in the public area or artists make a distinction between information gathered from publicly available information or third party interviews and information gathered directly from the subject or from private papers. Specifically exempted from ethics review is information gathered from demonstrations, political rallies or public meetings, since it is expected the participants are seeking public visibility. Canadian Panel on Research Ethics, *op.cit.* Article 1.1 and 2.3.

⁵³ AHA, *op. cit.*

⁵⁴ Cary Nelson, “Can E.T. Phone Home? The Brave New World of University Surveillance,” *Academe* (2002), available online at <http://www.aaup.org/AAUP/pubsres/academe/2003/SO/Feat/nels.htm>; see also, Daniel Bradburd, “Fuzzy Boundaries and Hard Rules: Unfunded Research and the IRB,” *American Ethnologist* 33, No. 4 (2008): 492 – 498.

⁵⁵ Rena Lederman, “The Perils of Working at Home: IRB ‘Mission Creep’ as Context and Content for an Ethnography of Disciplinary Knowledges,” *American Ethnologist* 33, No. 4 (2006): 482–491.

⁵⁶ Bradburd, *op.cit.*

anthropological inquiries. Bradburd admits that he ignores the rules for research into non-controversial things like spicy food eating habits, but applies for IRB approval for questions related to drug or alcohol use, essentially deciding for himself what research is benign enough not to need oversight.⁵⁷

E. Political Science and Public Policy

Much of modern social science is based on quantitative research involving statistical analysis of large data bases. Here individual identities are not known, nor would it be necessary to reveal them. Nevertheless, since human subjects are involved, most of this research must be submitted to IRB committees.

For qualitative research or mixed method research, the IRB process poses much greater challenges. In 2008, the American Political Science Association sponsored a five part symposium on IRBs, and the editor, Robert J.P. Hauck summarized the findings as follows:

Now as in the past, IRBs have no consistently applied metric for measuring risk and corresponding levels of IRB review.... the review process has not and perhaps cannot accommodate survey methods and ethnographic field research. The pace of the IRB review process continues to hinder undergraduate and graduate empirical research. IRBs' rigid interpretations of requirements produce logically inconsistent directives such as when researchers are told to destroy data they diligently collected and anticipated sharing in order to protect research subjects' anonymity.⁵⁸

Since concepts such as benevolence and justice are used by IRBs to evaluate research proposals, there is the danger that ideology may affect their judgment. The OHRP Researcher's Guide cautions:

One special instance of injustice results from the involvement of vulnerable people. Certain groups, such as racial minorities, the economically disadvantaged, the very sick and the institutionalized may be continually sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their

⁵⁷ Ibid.

⁵⁸ American Political Science Association Symposium, « Protecting Human Research Participants, IRBS and Political Science Redux, » *PS* ,41 July, 2008. See also Zachery M, Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences* (Baltimore: Johns Hopkins University Press), 2010.

frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for reasons of administrative convenience or because they are easy to manipulate because of their illness or socioeconomic status.⁵⁹

A more reasonable interpretation of why the above groups are more frequently studied (if the generalization is true) is that researchers are moved by their plight to do research that might mitigate their condition.

A recent book on higher education in the United States titled “*Wannabe U: Inside the Corporate University*” illustrates some of the problems IRBs can cause in altering the research process.⁶⁰ Professor Gaye Tuchman, a sociologist, was not just being cute with her title. Although almost everyone knows the book is about her employer institution, the University of Connecticut, she will not confirm that fact. Her local IRB insisted that she obscure many of the identities of the university officials she describes. As one reviewer noted:

Under the terms approved (and in some cases insisted upon) by her institutional review board, no real names are given for those at Wannabe. In fact she said in an interview that she “promoted and demoted people” and changed personal details to hide their identities.⁶¹

Under these circumstances, how can readers know if the author got the story right or put events into proper perspective? How could the scientific bedrock principle of replicability be possible?

Under some interpretations of IRB rules some of the great classics of the social sciences could not have been written nor have had the impact they have attained. For example, in his seminal work, *Bowling Alone*, which uses statistics and anecdotes to document the decline of civic life in America, Harvard sociologist Robert Putnam begins his book by describing the dissolution of the Glenn Rock Pennsylvania Bridge Club, the Roanoke Chapter of the NAACP and the annual book

⁵⁹ National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report*.

⁶⁰ Gaye Tuchman, *Wannabe U: Inside the Corporate University*, (Chicago: The University of Chicago Press, 2009).

⁶¹ Scott Jaschik, “Wannabe U,” *Inside Higher Ed*, October 6, 2009.

sale of the Washington D.C Vassar alumnae among others.⁶² Real organization's and people's names were used, though presumably there is some pain to the former leaders of these civic failures. Nevertheless, the detail in Putnam's work adds greatly to its credibility. One wonders if the University of Connecticut IRB was not more concerned about its institutional reputation, than IRB principles of benevolence and justice.

F. Journalism

In many American universities, there are schools or departments of journalism which teach graduates and undergraduates that craft. Journalism often requires research into the lives of both public and private figures and as such there are often legal conflicts. The First Amendment in the U.S. constitution specifically protects freedom of the press. Judicial decisions have restricted the use of prior censorship as described earlier and have restricted the use of libel laws that might circumscribe press freedom.⁶³

The IRB process which insists on both prior censorship and standards which require human subjects to be treated with beneficence does not mesh well with journalistic practice. Leon Dash, a professor of journalism and law at the University of Illinois at Urbana-Champaign, asserts one of the main goals of journalism is to expose corruption and abuses of power. How can journalists do this, he asks, if some topics can be ruled "too controversial" by their IRB? ⁶⁴ A board of administrative preclearance is a dangerous force for keeping secret things that the public has a right to know. Journalists, he argues, need to be free to confront powerful people. Dash may take this question personally; he won the 1995 Pulitzer Prize for Explanatory Journalism on the topic of teen pregnancy, which is research involving what may be the most sensitive protected status, pregnant

⁶² Robert D. Putnam, *Bowling Alone* (New York: Simon & Schuster, 2000).

⁶³ *Bantam Books, Inc. v. Sullivan*, 372 U.S.58 (1963), *New York Times Co. v. United States*, 403 U.S. 713 (1971), and *Hustler Magazine v. Falwell*, 485 U.S. 46 (1988)

⁶⁴ Leon Dash, "Journalism and Institutional Review Boards," *Qualitative Inquiry* 13, No. 6 (2007): 871-874.

and underage subjects. According to Dash, forcing journalists to unnecessarily hide the identity of their sources also weakens the credibility of their stories, as they cannot prove the validity of their research if they are challenged.⁶⁵

The late Margaret Blanchard, who was the William Rand Kenan Jr. Professor of the School of Journalism and Mass Communication at the University of North Carolina at Chapel Hill, claimed that IRB regulations affect the ability of journalism professors to teach. Journalism students need to be trained to follow ethical standards designed specifically with journalism in mind. IRB rules are designed for biomedical and behavioral research which have nothing to do with journalism.⁶⁶ Blanchard argued that there were a number of other negative effects of IRBs on journalism. In general, IRBs are ignorant of the realities of conducting journalistic research. Forcing journalists and journalism students to use informed consent procedures makes journalists seem incompetent and distrusted by their own university because they would need interviewees to sign a detailed consent form before anyone can be interviewed. The Chapel Hill IRB requires that questions asked in telephone interviews be scripted and approved.

Perhaps aware of these tensions, at least nineteen colleges and universities have created a journalism exemption on their IRB websites. These exemptions, however, may not be consistent with IRB regulations. A 1995 OHRP report states that “[i]nstitutions and IRBs may not create new categories of exempt research under 45 CFR Part 46.”⁶⁷ However, OHRP rarely seems to enforce this ruling, although in February 2009, it did cite an unnamed institution for applying an exemption that exceeded the exemption list in Title 45, Part 46.⁶⁸ This laxity may explain why IRBs at a

⁶⁵ Ibid.

⁶⁶ Margaret Blanchard, “For the Record: Should All Disciplines Be Subject to the Common Rule? Human Subjects of Social Science Research,” *Academe* (May – June 2002), available online at <http://www.aaup.org/AAUP/pubsres/academe/2002/MJ/For+the+Record/FTR2.htm>.

⁶⁷ Gary Ellis, “Exempt Research and Research That May Undergo Expedited Review,” (1995), correspondence sent on behalf of OPRR, available online at <http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm>.

⁶⁸ Office for Human Research Protections, “Compliance Oversight Activities: Determinations of Noncompliance,”

number of universities still have journalism exceptions.

Why would an academic institution's IRB create an exception for journalism? There are both pragmatic and theoretical explanations. It may want to avoid being sued on First Amendment grounds by members of its own journalism department or entering into confrontation with the local media. Or it may believe that journalism is not engaged in research that leads to generalizable results which is the touchstone of IRB authority.⁶⁹ This rule which seems to be a carryover from the biomedical origins of IRBs is puzzling. If the purpose of IRBs is to treat human subjects with autonomy, benevolence and justice, why exempt hostile inquiries about particular individuals, institutions or groups where the researcher is not intending to generalize?

Furthermore, a basis for exempting research by journalists, the assumption that journalists do not produce generalizable research is also empirically wrong as almost any regular reader of a good newspaper would know. Alexander Bush has investigated this question by examining Pulitzer Prize winning stories in the Investigative Writing and Public Service categories from 2005-2009.

⁷⁰ These articles concerned the use of retired military officers to promote Pentagon policies in exchange for access to classified documents about contracts, Chinese drug manufacturers using harmful cheap ingredients, poor regulation of dangerous children's toys, corruption in Alabama community colleges, dangerous working conditions on the Las Vegas strip, and poor care of military patients at Walter Reed Hospital. All of these pieces ended in making generalizations

OHRP, 2009, available online via <http://www.hhs.gov/ohrp/compliance/findings.html#E0>.

⁶⁹ See for example, Texas Tech University which states that journalism, "fall[s] outside the jurisdiction of the IRB because [it does not] have the purpose of contributing to generalized or [is not a] systematic investigation. Policies and Procedures, Institutional Review Board. Texas Tech University, March 12, 2009. Austin Peay University draws this distinction, "While its true that journalists can engage in 'systematic' investigation, generally speaking, the end results of their interviews is simply reported (or quoted) and synthesis or interpretation of what was said is not offered and no attempt is made to generalize." Frequently Asked Questions. IRB Home Page. Austin Peay University, March 11, 2009.

⁷⁰ Alexander Bush, "Journalism, Academic Freedom and the IRB; An Analysis of the Journalism Exception," independent study paper, UMBC, May 11, 2009.

harmful to private individuals and institutions and none of them were subject to IRB-like procedures.

V. Conclusions

IRB rules view social science and humanities research from a biomedical and psychological perspective. The “autonomy, beneficence and justice” concepts are useful constructs for a therapeutic approach to human problems. In this approach, the search and dissemination for truth are less important than the healing of persons. Moral and policy judgments about the behavior of patients may impede treatment and therapy and are often considered inappropriate. A battered wife and a drug addict who harms himself should receive equally professionally appropriate care.

The responsibilities of social science, humanities, and journalistic professionals, however, are different. They are in truth seeking, not healing professions. They often disagree among each other about the definition of “autonomy, beneficence and justice.” Indeed those concepts are the very stuff of political debate and have been for centuries. Consider the controversies over the recent health care legislation in the United States as a prime example. Which of the policies debated will best advance “autonomy, beneficence, and justice” will not be known for some time and there likely will be disagreement. There are often unintended consequences from any social program.

The best that social scientists and journalists can do is to seek and report the truth as accurately as possible within the limits of time and space available. If they err, there are professional associations that can discipline them and individuals have recourse to libel law. They should not try to prejudge what constitutes justice or turn that judgment over to any institutional committee. “The truth will set you free,” but frequently it does not make individuals or society feel happier or healthier. One has only to open a newspaper, watch the evening news or scan the public policy section of a book store to realize that reality.

There are reckless institutions and immoral people and institutions, who, if empowered, can cause enormous damage to individuals, groups, and society. Their behavior will always be controversial, when discovered, but, if left undiscovered, the consequences are much worse. Can a concept of informed consent work, if the purpose of the investigation is to investigate possible misdeeds? Who would consent to sharing information or records, if informed first about the risks they were running to their income, status or reputation? Such research may be a messy business, but how much better off the world would have been if tough accurate reporting by academics and journalists about the packagers of subprime mortgages, the marketers of risky derivatives, the creators of investing ponzi schemes, and the short term myopia of financiers had existed before they could produce such havoc in the world's markets. What research and reporting "beneficence" should apply to them once their ignorance and greed was discovered?.

Why do social scientists and journalists, let alone IRB committees, have the responsibility to do more than gather facts fairly and report the results accurately, but also have to determine what "justice" requires? Isn't it the responsibility of the judicial system to determine what "justice" requires when dealing with alleged professional malpractice, business and union corruption, slumlords, human traffickers, or narcotics dealers, etc.?

What is the universities' obligation when faculty decide to investigate these activities? If IRBs limit research approaches or insist that the objects of investigations not be named, what concept of justice or academic freedom are they contributing to? It is understandable that universities must utilize IRBs as a condition of receiving federal funds,⁷¹ but it is less comprehensible that they have applied IRB standards to unfunded research. Perhaps the best explanation is that the modern university, always in the process of raising funds, has become extremely risk averse and does not

⁷¹ Zachery Schrag reports some states, such as Maryland and Virginia, have statutes applying federal rules to human subject research in the states, but it is not clear they are enforced.

want to antagonize any interest group or its legislative allies. If a university's motivation is protection against research that is unfairly biased, the peer review for faculty and grading process for students should be a sufficient check and balance. If a researcher libels or slanders someone, there is legal recourse. If a university's motivation is simply the avoidance of controversy, then society pays a steep price. To permit self-selected committees to restrict the inquiry and communication of other members of the university community is to run the risk that the ideological imbalance of the academy and the temptation to political correctness will influence the definition of "justice."

In this era, there is a particular societal peril when universities make it more difficult for social scientists and academic journalists to investigate controversial subjects. The newspaper industry in some areas is near collapse and, in almost all others, has shed reporters. State and local television reporting is shrinking, replaced by a focus on sports, celebrities, and weather. That leaves public opinion to be overly shaped by talking heads and bloggers, whose professional codes are evanescent, if they ever existed. University based research on important matters of social policy has never been more important to a public inundated by infomercials and political sound bites.

IIRBs have existed in academic life for several decades. As a device for training researchers and providing ethics advice on a voluntary basis in the social sciences and journalism, they provide a useful function. As a mechanism that can lead to censorship, however, they are not accountable and their rules don't fit all disciplines. Federal regulators and university administrators have grown comfortable with them, even though very little is known about how they actually apply the rules from campus to campus. Until recently, it seemed unlikely that any serious debate about their authority would occur, but there is, however, a growing challenge from some professional associations. The American Association of University Professors has suggested a new standard that would solve many problems:

Research on autonomous adults whose methodology consists entirely in collecting data by survey [or] conducting interviews [should] be exempt, with no proviso and no requirement of IRB approval of the exemption.⁷²

Realistically, few, if any, universities would be willing to challenge federal agencies about the review of funded research. Much campus research is unfunded, however, and universities could adopt the AAUP proposal for unfunded research for a trial period. This would create a controlled experiment, after which the benefits and costs of IRB review could be better evaluated. The scope of IRBs mandates should be reexamined and universities should strengthen the priority of academic freedom as a value on their campuses.

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⁷² Of course, the term autonomous adults was chosen to exclude children, persons incarcerated or not mentally competent.

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