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## **Tangible and Intangible Costs of “Protecting Human Subjects”: The Impact of the National Research Act of 1974 on University Research Activities**

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### **Abstract**

This article (1) examines the overall structure of regulatory research oversight in the United States; (2) details the origins and evolution of federal legislation pertaining to the protection of human subjects in biomedical and behavioral treatment and research; and (3) describes the expansion of oversight regulation from biomedical and behavioral treatment areas to the social sciences. In addition, the paper describes three areas identified by compliance administrators as susceptible to abuse: (1) informed consent, (2) assessment of risks and benefits, and (3) equitable selection of human subjects. There is a discussion of existing tensions in the implementation of oversight policies and procedures. Finally, the paper identifies four issues for future consideration: (1) scope of the mandate regarding protection of human subjects, (2) impact on the nature of research being undertaken, (3) financial burden of compliance and oversight activities, and (4) ethical standards, constraints, and potential.

## Introduction

The social history of the United States abounds with examples of reactive public policy initiatives: compulsory school attendance laws, minimum age requirements for work, health and safety laws in the workplace, to name a few. Within the past quarter century, public policies have emerged regarding ethical treatment of patients and experimental subjects, as well as the ethical conduct of researchers. The laws and accompanying regulations provide a safety net against a repetition of notorious abuses of patients and experimental subjects, and advance the fundamental protections accorded all those who live in the United States.

In the aftermath of World War II, increased national and international scrutiny of the human rights violations during the War led to formal assertions of human rights and of the limits of infringements on those rights. The newly formed United Nations established a Commission on Human Rights, and approved *The Universal Declaration of Human Rights* to delineate the rights of individuals, and the responsibilities of governments in protecting individuals from human rights abuses. Such abuses included, of course, physical and psychological abuse, loss of legal rights and due process, and intimidation and torture. They also included less minatory, but significant, abuses such as: loss of privacy, treatment without consent, failure to be informed of consequences, and withholding of information.

Public policy in the United States regarding the rights of individuals has evolved considerably in recent decades, the result of court decisions, state and federal legislation, advocacy group activities and initiatives, and Presidential executive orders. The National Research Act of 1974 represents a statement of principles to shape public policy about the conduct of research. The implementation of public policy, however, is inevitably imperfect because the definition of "well-being", the fundamental building block of all public policy, can vary from group to group. That is, "good" public policy for one group can be injurious to another group. In light of past abuses, public policies to protect individuals from undisclosed medical experimentation is indisputable, but what happens when those policies impose burdens on the conduct of other types of research, such as social science research in classrooms?

This paper (1) examines the overall structure of regulatory research oversight in the United States; (2) details the origins and evolution of federal legislation pertaining to the protection of human subjects in biomedical and behavioral treatment and research; and (3) describes the expansion of oversight regulation from biomedical and behavioral treatment areas to the social sciences. In addition, the paper describes three areas identified by compliance administrators as susceptible to abuse: informed consent, assessment of risks and benefits, and equitable selection of human subjects. Finally, there is a discussion of the existing tension in the implementation of oversight policies and procedures.

## The Origins of Regulatory Oversight in Research Activities

The development of laws, procedures and protocols to ensure the protection of individuals' rights when they are the subjects of research gained momentum in the 1960's, and the National Research Act was implemented in 1974. In the general environment of increased concern about the rights of individuals, there were revelations in the 1960's of abuses which had occurred in medical and psychological research. Perhaps the most dramatic example brought to public attention was the report of the "Tuskegee Experiments." Beginning in 1930, and continuing until 1973, a group of African-American men were monitored to see the progressive effects of untreated syphilis. When it became possible to cure syphilis, that information was withheld from the patients, and their disease progressed even though medical treatment was available.

The work of Stanley Milgram, for example, called attention to the use of "naïve" subjects. Beginning in 1961, Milgram conducted a series of experiments in New Haven, Connecticut, working with uninformed participants who were led to believe they were participating in research on the effects of punishment by electric shocks on the ability to learn. The "experimenter" who gave instructions to the participants and the "learners" who received the shocks were paid actors; in actuality, the electrical apparatus was merely a prop, and no shocks were administered. Writing about those experiments and the ensuing public outcry, Blass has said: "Although subjects were told about the deception afterward, the experience was a very real and powerful one for them during the laboratory hour itself" (2002).

Milgram's work and the Tuskegee experiments focused attention on the rights of individuals to be fully informed and to give consent. Public awareness led to public scrutiny, and, ultimately, to public policy.

It is now clear that the practice of conducting research on individuals from whom permission had not been sought was widespread in the first half of the twentieth century, and information continues to emerge about such practices. In the area of psychological research, repeated incidents have been brought to public attention in which subjects were either not informed, or informed falsely, about aspects of experimental research in which they were participating. For example, in the summer of 2003, 11 individuals sued the University of Iowa which had permitted research to be conducted on them without their knowledge or consent in the 1930's. In Wendell Johnson's "Monster Study," children at an orphanage were subjected to relentless criticism for any imperfections in their speech to see if such criticism could cause them to become stutterers (Reynolds, 2003). Referring to this, the Director of the University of Pennsylvania's Bioethics Center, Arthur Caplan, stated that 60 years ago ethical rules did not exist, and experiments were done using minorities, disabled children or prisoners "because you didn't think of them as morally equivalent to others."

In July 1974, President Nixon signed into law the National Research Act in response to well-publicized past abuses, as well as to scientific advances which held the potential of opening new avenues of inquiry and treatment. The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, charged with identifying "basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles" (*Belmont Report*).

Five years later, the Commission submitted *The Belmont Report*, which became the basis of current regulations and practice regarding the protection of human subjects. Dr. Kenneth John Ryan, Chief of Staff of Boston Hospital for Women, chaired the eleven member committee. Because most of the concerns leading to the creation of the Commission involved experiments that had physical manifestations, the committee members' expertise was in science, not social science. The sole member of the committee with a background in a social science discipline was a psychologist, but his training and expertise was in physiological psychology.

The Commission's principal activity was to "identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles" (*Belmont Report*). Given the composition of the Commission, the notorious abuses by the Nazis abroad, and the Tuskegee experiments in the United States, it was probably inevitable that emphasis be placed on medical experiments. Indeed, the *Report* refers to the basic principle of the Hippocratic Oath of "doing no harm."

The *Belmont Report* articulated ethical principles and proposed practices resulting from adherence to those principles. Three specific recommendations for practice emerged:

- the need for informed consent,
- the objective assessment of risks and benefits, and
- the equitable selection of research subjects.

## **Structures and Procedures to Ensure Compliance**

Although the codification of laws, procedures, protocols, and assurances pertaining to human subjects initially emphasized medical research, there was an extrapolation to psychological, emotional, and behavioral research after passage of the National Research Act of 1974. Today, a quarter century later, the breadth of its applicability continues to evolve.

There is, however, no evidence in the documents related to the National Research Act, or the subsequent Belmont Conference Reports Act that there was legislative intent to bring social science, non-medical research under the umbrella of human subjects protection. The process of inclusion appears to have been incremental, gradually encompassing direct experimental interactions (as in the Milgram experiments), to interviews, surveys, and questionnaires, and then to observation.

Over time, the scope of oversight compliance has come to encompasses three broad areas:

- *Issues regarding safety*, particularly when hazardous materials are to be used;
- *Issues related to the well being of human subjects* including minimizing physical and psychological risks, as well as ensuring that any person involved is apprised of risks and adverse consequences; and
- *Issues related to privacy* and the protections in place to ensure confidentiality.

The *Code of Federal Regulations* provides exemptions in some areas of research, but these are largely confined to activities related to educational performance, and which, for the most part, take place in schools or other educational settings (see Appendix A).

For the most part, oversight of compliance has been the responsibility of the Department of Health and Human Services. HHS monitors all research involving human subjects if any funding from HHS has been provided. In addition, the Food and Drug Administration (an agency within HHS) monitors all research pertaining to research on products regulated by the FDA, whether or not federal funding is involved. Other federal agencies have independent authority to regulate and monitor human subjects research activities, and have similar criteria and procedures in place.

Since the passage of the National Research Act, federal policy regarding human subjects research has been based on the principles of decentralization and institutional responsibility.<sup>1</sup> The principal mechanism by which this has been implemented is through the creation of Institutional Review Boards (IRB's). Although guidelines are issued about the size and composition of individual IRB's, institutions select their own members and establish their own operating procedures. IRB approval is a prerequisite for conducting research, and institutions may not permit research to be conducted without such approval; institutional approval, however, may be subject to additional review by federal agencies, which has the authority to withhold final approval.

In practice, for reasons of consistency and efficiency, many universities make IRB review a condition for any research undertaken at the institution, whether or not federal funds are being used. This has two consequences: first, it significantly increases the workload of IRB's; and, second, it

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<sup>1</sup> Until 1981, oversight was centralized, first in DHEW, and then in HHS, and then decentralized to institution-based IRBs.

causes some researchers to pursue their work independently of their institutional affiliation (Pritchard, 2001).

The degree to which research in the social sciences would be affected by the implementation of the National Research Act and the principles of the *Belmont Report* was not fully understood until after Institutional Review Boards were in place, and had begun systematic reviews.

Although few institutions are totally free of compliance requirements at some level, compliance burdens fall disproportionately to a relatively small number of institutions receiving substantial support from the federal government. In 1999-2000 (the latest year for which data are available), there were 92 institutions receiving more than \$100 million in federal support. Federal funds allocated to only 120 institutions comprise 74 % of total funding given to all degree granting institutions (NCES, 2003).

In reality, approximately 10% of the more than 2000 existing IRB's process 75% of all compliance requests. Thus, a single faculty member at a liberal arts college doing experiments with mice warrants the formation of an IRB.<sup>2</sup> Infrequent convenings of IRB's can lead to inefficiency, even error. In that sense, larger institutions have the advantage of readily available apparatus, and relevant experience.

### Tensions in Implementing Oversight Policies and Procedures

Weighing *abstract* values (such as the right to privacy and the right to be fully and clearly informed of potential treatment risks) against *tangible* elements (such as per unit costs, time, and money) can be difficult and time consuming. The authors have examined the tension between dissimilar inputs and outputs in the field of compliance, concluding that adherence to "the rules" often takes precedence over sustaining or achieving more intangible goals.

Since 1981, when the present decentralized system of IRB's was implemented, serious concerns have emerged about the tangible and opportunity costs of maintaining the present oversight system. This is particularly relevant in light of how labor intensive the system is, both for researchers and IRB members and administrators. Pritchard (2002) points out that 17 different federal agencies "share the same regulations for the research they sponsor."<sup>3</sup> Essentially, the federal regulations, known as the "Common Rule," require any research facility receiving federal funds to submit a contract "in which the research facility promises to abide by the Common Rule for all of its research that involves human subjects, whether it is privately or federally funded" (Alvino, 2003, p. 893).

In reality, however, "tradeoffs" between "good" public policy and costly overregulation have tended to place emphasis on following the details—rather than the intentions—of efforts to protect "human subjects." The result has been the creation of a huge infrastructure of review boards, compliance officers, monitors, and evaluators to ensure that all procedures are followed. What is at risk in emphasizing compliance and regulation *over* intentions and goals is fundamental: whether

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<sup>2</sup> Although most institutions undertaking research have their own IRB's, FDA regulations do permit an institution without an IRB to arrange for an "outside" IRB to be responsible for initial and continuing review of studies conducted at the non-IRB institution (<http://www.fda.gov/oc/ohrt/irbs/default.htm>) 1998.

<sup>3</sup> These regulations are referred to as the *Common Rule* because they are applied to so many different government offices. See Title 45, CFR, Part 46, which details the policies in place for United States HRSP (Human Research Subject Protection) policy.

compliance is *process or product*.

What, then, are some of the factors contributing to tensions in implementing IRB procedures, and how do existing tensions impede overall compliance effectiveness?

- **One Size Fits All**

In referring to the Common Rule, Pritchard states that “regulation in general and these regulations in particular, are a blunt instrument” (Pritchard, 2002). The imposition of medically based standards of ethical treatment to social science research has frustrated evaluators and led to confusion on the part of IRB’s (Oakes 2002, p. 448). Although there have been some attempts to introduce flexibility, the central idea of the regulations is to have as many common elements as possible. Because of the great variation in research protocols among different fields of study, IRB’s frequently seek a common denominator as a means of creating efficiencies. But, in doing so, important methodological issues can be overlooked, or dismissed as only minimally different from the “common” approach.

Most IRBs have provisions to send a research protocol to an external reviewer for review and approval (Evans 2003), but, in practice, time pressures preclude the use of such reviewers. This means that many IRB’s use criteria that can filter out only the weakest methodologies.

- **Lack of Training**

In a 1998 evaluation of NIH protection of research subjects procedures, commonly referred to as the “Bell Report,” the authors report that more than 85% of IRB chairs and administrators indicated that more education and training should be provided (Bell, Whiton, and Connelly 1998). In most institutions, the internally appointed IRB members are “volunteers” serving as part of their university service commitment, often on a rotating basis of two or three years terms. This was confirmed in a telephone survey of twelve institutions<sup>4</sup> conducted by the authors. The survey results indicate that seven of the twelve institutions had relatively short terms (three years or less) for chairs, and only two of the twelve provided support for chairs to attend external “training” programs. In addition, the survey revealed that none of the twelve institutions had fewer than three new members (three year average) each year (Jacobs and Zonnenberg 2003). (The results of the survey are reported in Appendix B.)

Problems arising from lack of training of IRB members have been identified as among the most difficult challenges to institutions dealing with compliance issues. The “Bell Report” indicates that 21% of investigators interviewed regarded lack of expertise (or bias) as a “problem” in their research (1998).

- **Over-Attention to Detail**

Two initiatives by the federal government have attempted to simplify the labyrinth of details with which institutions must deal. These are the adoption of the Common Rule (described above), and the use of the Multiple Project Assurance. The former attempts to codify procedural and compliance rules among multiple federal agencies, and the latter sets a common standard for human subjects protection which is applied prior to seeking external research funding.

In part, this focus on the rules exists because the federal Office for Human Research Protections has shut down all research at particular (and prominent) institutions because of

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<sup>4</sup> The twelve institutions were randomly selected from among the top eighty institutions receiving the largest amounts from the federal government (NCES, 2002, Table 340).

violations of human subjects protections, in some cases leading to deaths (Marshall 2003; Oakes 2002; Singer and Levine 2003). With this impetus for regulation, it is hardly surprising that IRB's have a strong focus on the application of the rules. Further, recent debates over the ethics of research in developing nations contributes to this emphasis on the word of law (Marshall 2003).

Despite this, institutional administrators report that over-attention to detail can obscure the larger—and more abstract—issues of intention, consequences, and benefits. Pritchard notes that the tendency to determine whether or not a particular protocol or project “conforms to the rules” can lead to an assumption “that conforming to the rules is both necessary and sufficient to determine that a given course of action is right” (Pritchard, 2002).

#### ▪ **Lots of Work With Few Results**

As noted above, 120 institutions receive 75% of all research funding. This compression means that a relatively small number of institutions process and review a great many applications. Given the narrowness of specialization in some research areas, those submitting applications are most often best able to make informed judgments. Since they cannot, IRB's must seek external reviewers or spend an excessive amount of time assessing requests.

In another component of the telephone survey conducted by the authors, the institutional representatives were asked how many applications for human subjects protection were not given final approval in the preceding year: under five, more than five, or more than ten. Two of eleven institutions (one institutional representative could not respond) had more than ten, and two had under five. Seven had between five and ten (Jacobs and Zonnenberg). One institutional representative said: “we manage to do a good job of fixing problems in applications we receive, but we seldom reject them permanently because in the end we defer to P.I.s.”

Rubin contends that IRB's have steadily increased their “attention to detail” because lists of errors in procedures and omission of required components are easy to quantify, and become a justification for a process which often does not result in a large number of unapproved applications (2001).

Taken together, these four factors (One Size Fits All, Lack of Training, Over Attention to Detail, Lots of Work With Few Results) comprise the major sources of tension in the debate about compliance as *process* or *product*. If compliance is the vehicle through which human subjects research can be improved and subjects further protected, then more emphasis needs to be placed on the principles articulated in the Belmont Report,<sup>5</sup> resulting in a better and more responsive research product. If, on the other hand, compliance is a process of adhering and conforming to the established rules and regulations as well as to procedural safeguards and assurances, then the present decentralized oversight system affords institutional flexibility within the parameters of federal regulation.

In either instance, quality control remains uneven. It is frequently left to the interpretation of administrators committed to efficiency and efficacy and to IRB members who are untrained in the work to be done, and who have little practical experience. The immediate challenge, then, is to re-examine institutional compliance from the perspective of process and product, and to implement an

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<sup>5</sup> The Belmont Report contains these subject areas: Respect for Persons, Beneficence, Justice, Informed Consent, Assessment of Risks and Benefits, and Selection of Subjects.

effective quality control system.

## Conclusion: Issues for Future Consideration and Further Study

It is scarcely more than a quarter of a century since the passage of the National Research Act, and the promulgation of regulations, protocols, and procedures related to the protection of human subjects. Each year, more than two thousand individual Institutional Review Boards submit reports to federal agencies. All of the one hundred largest school districts in the United States have compliance review units, with staffs ranging in size from under a dozen to more than several dozen. Every state has a regulatory office charged with oversight for public education institutions.

Regional accreditation agencies for higher education have specific criteria pertaining to institutional compliance. In fact, more than half of all compliance activities are not in the areas of biomedical and behavioral treatment and research, but in social science related disciplines, notably education. Indeed, in October 2003, the federal Office for Human Research Protection (part of the Department of Health and Human Services) conceded that oral history interviews do not need to be regulated by institutional review boards. In reporting on this, the *Chronicle of Higher Education* stated that: “[oral-history] scholars have argued that colleges have interpreted federal regulations too broadly and moved to regulate research projects that pose little or no risk to interviewees” (Brainard, 2003). Nor is this an isolated example of overly broad interpretation.

Another example can be seen in the trend among some Institutional Review Boards to regard “passive consent” (the idea that unobtrusive low impact activities, such as videotaping children in a classroom or recreation setting, should not require proactive consent) as a violation of procedural compliance and as not permissible.

The issues for further study fall into four broad areas:

- **Scope of the Mandate Regarding Protection of Human Subjects**

What evidence is there to indicate that the expansion of oversight beyond biomedical and behavioral treatment and research was intended by those who prepared *The Belmont Report*? Should the scope of the present oversight mandate be modified in light of the sometimes-excessive burden imposed by Institutional Review Boards’ interpretation of various regulations?

- **Impact on the Nature of Research Being Undertaken**

What evidence is there to indicate that some areas of inquiry and some methodologies are not being pursued or utilized in order to avoid some of the cumbersome and time consuming aspects of current oversight regulations? Are there disciplines in which valuable research is not being undertaken because researchers want to avoid the complications associated with compliance?

- **Financial Burden of Compliance and Oversight Activities**

The costs of these activities are typically paid for in one or more of the following ways: through direct costs budgeted in research proposals, by allocating a portion of indirect cost recovery (“overhead”), and by incorporating compliance activities into the institution’s overall administrative structure. How much is too much? Are there efficiencies which could be implemented to reduce institutional costs? Can a waiver system be developed to reduce the amount spent on oversight of “low risk” activities?

- **Ethical Standards, Constraints, and Potential**

The fundamental ethical conflict in human subject research is whether benefit to the larger community can be an appropriate rationale for research and experimentation affecting individuals. The lesson painfully learned from the abuses of the mid-twentieth century is

clear: even if the potential benefits are profound, risks to individual must always be minimal, undertaken with their knowledge and consent, and with the high probability that they will not be harmed as a consequence of their participation.

There can be little doubt that the movement to increase protection for human subjects, and to ensure compliance with established standards has reduced the number of people placed "at risk" without their knowledge or consent. As researchers, research administrators, policy makers, and legislators look to the future, they must do so weighing the tangible and intangible costs of compliance, and with the knowledge that every system of accountability can be revised and improved through an examination of past experiences.

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## Appendix A: Excerpt from Code of Federal Regulations

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (i) research on regular and special education instructional strategies, or
  - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) 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.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
  - (i) the human subjects are elected or appointed public officials or candidates for public office; or
  - (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
  - (i) Public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
  - (i) if wholesome foods without additives are consumed or
  - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Code of Federal Regulations, Title 45 (Public Welfare), Part 46: Protection of Human Subjects (December 13, 2001). Washington DC: Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks.

## Appendix B

<b>Survey of Twelve Institutions Regarding Terms of Service and Training<sup>6</sup></b>				
<b>Terms of Service</b>	<b>1—2 years</b>	<b>3 years</b>	<b>4 years</b>	<b>Indefinite</b>
How long does Chair serve?	4	3	1	4
Training Program for Chair?	Briefing	Briefing (2) Workshop (1)	Conference	Conference Briefing Workshop (2)
Does Chair serve first as Vice Chair?	Sometimes (2) Yes (1) Don't Know (1)	Yes (1) Sometimes (2)	Yes	Sometimes (1) Yes (2) Rotates (1)
Number of new members each year? (three year average)	4 (2) 3 (2)	3 (2) > 5 (1)	3	4 (2) 3 (1) > 5 (1)
Training Program for new members?	Briefing (3) Informal (1)	Briefing (2) Informal (1)	Workshop	Briefing (2) Informal (1) Workshop (1)

**Notes:**

"Briefing" refers to a program or activity done by the administrative staff for new IRB members.

"Workshop" refers to an internal institutional program in which new members are presented with information and examples of issues they will likely encounter. The length of the workshops ranged from a half day to one and a half days.

"Conference" refers to a formal program external to the institution which members attend for orientation and training.

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<sup>6</sup> Jacobs, F. and Zonnenberg, A. (2003). Telephone Survey.

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