Protecting the Human Subjects of Social Science Research —The Role of Institutional Review Boards

by Don Reynolds

Current and proposed reforms of the regulatory schema for protecting human subjects of research have focused attention on Institutional Review Board (IRB) responsibilities. Consensus on the need for strengthening the oversight of these boards is all but certain — with the exception of research in the social and behavioral sciences, where an argument for less oversight is being made. The thesis in this article is that respecting the salient features of research in the social and behavioral sciences will ameliorate the tensions leading to this demand and offer better protection to the subjects of social and behavior studies.

Institutions that engage in human subject research maintain administrative bodies known as Institutional Review Boards (IRBs). Institutions charge their IRBs with protecting the rights and welfare of the people who participate in studies conducted under their auspices.

IRBs first appeared following World War II, and became prominent after 1974, when the federal regulations of human subject research identified them as fit mechanisms for protecting research participants. In 1981, following a significant revision of Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations pertaining to human subject research, IRBs became ubiquitous. Though the exact number of IRBs is unknown, DHHS estimates that there may be as many as 5,000 active IRBs in the country.

Prior to 1988, reforming the capability of IRBs to accomplish the regulatory schema for protecting the human subjects of research was not seriously questioned. However, in June 1998, the DHHS Office of Inspector General released a report, "Institutional Review Boards: A Time for Reform," claiming that "the effectiveness of IRBs is in jeopardy." The report supported this claim with five findings.

> [IRBs] face major changes in the research environment. They review too much, too quickly, with too little expertise. They conduct minimal continuing review of approved research. They face conflicts that threaten their independence. They provide little training for investigators and board members. Neither IRBs nor [DHHS] devote much attention to evaluating IRB effectiveness.

To ameliorate these problems, the report recommended six reforms:

- Recast Federal IRB requirements to grant IRBs greater flexibility and hold them more accountable for results.

- Strengthen continuing protections for the human subjects of research.

- Enact Federal requirements that help to ensure that investigators and IRB members are adequately (informed) about and sensitized to human subjects' protections.

- Help insulate IRBs from conflicts that can compromise their mission to protect human research subjects.

- Recognize the seriousness of the workload pressures that many IRBs face and take actions that aim to moderate them.

- Reengineer the Federal oversight process.

In April 2000, the DHHS Office of Inspector General revisited its criticism of IRB performance in a report titled, *Protecting Human Research Subjects: Status of Recommendations*. The report acknowledged that, "(S)ince the issuance of [the June 1988] report, human subjects protection has received considerable attention within [DHHS] and at the national level." Congressional hearings were held. Regulatory oversight responsibility for IRBs was relocated within DHHS to give it more prominence. A blue ribbon advisory group, the National Human Research Protections Advisory Committee, was created. The report concluded that "since June 1988, there [has been] a substantial increase in the enforcement of Federal human subject protection requirements. Several promising steps have been taken. But overall, few of the recommended reforms have been enacted."

Since then, human research subjects protection has continued to receive attention. Requirements to inform both IRB members and key research personnel about human subject protection issues have been implemented. A plan for obtaining the promise of every IRB to comply with federal human subject protection standards has been initiated. Prominent research institutions have been sanctioned because of IRB-related problems. The National Bioethics Advisory Commission (NBAC) released a lengthy report, *Ethical and Policy Issues in Research involving Human Subjects* (2000). Federal legislation to strengthen protections for human research subjects has been introduced (DeGette 2000). A proposal for accrediting human subjects research programs is being developed.

It has been twenty years since human subjects research issues last received such intense and sustained attention. With one exception, the intent of this attention is clear; institutions that engage in human subject research must take their duty to protect those subjects more seriously. However, notwithstanding the overall theme of ramped-up attention to the protection of human research subjects, the discussion about how we can protect the human subjects of social and behavioral research has headed off in the direction of less protection. The National Human Research Protection Advisory Committee is discussing whether the schema for protecting the subjects of social and behavioral science studies should be lower than the one for health science studies. The argument in favor of reduced protection for the subjects of social and behavioral research was made in the March 9 issue of *The Chronicle of Higher Education* (Brainard 2001).

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I chair the University of Missouri – Kansas City's Social Sciences Institutional Review Board. Each year we review of about 200 new social science studies. I am also a member of the University of Missouri – Kansas City's Pediatric Health Sciences Institutional Review Board, which each year reviews about 150 new pediatric health science studies. My day-to-day involvement with the IRB review of both health and social science studies informs my perspective for commenting on how health and social science studies are alike and how they differ with respect to the protection of human subjects.

The claim made in *The Chronicle of Higher Education* that the existing system of IRB review was primarily designed to protect human subjects from serious risks is not accurate. Actually the IRB review process described in the federal regulations provides three different review tracks based on risk – administrative review for many minimal risk studies, expedited review for other minimal risk studies, a convened-board review for riskier studies and studies involving vulnerable subjects. The article's claim that most social science research poses minimal risks to its human subjects is consistent with my experience. The majority of studies that come to the university's social science IRB require only administrative review. One should not conclude, however, that the expedited and full review tracks are not essential to this work.

We routinely review studies that pose more than minimal risk. My experience is that the existing system of IRB review provides a flexible three-track mechanism based on the risk that a given study poses for its human subjects. I know that the University of Missouri – Kansas City's social science IRB needs all three tracks, and that the track for minimal risk studies is not unduly burdensome to investigators.

Following the June 1998 report of the DHHS Office of Inspector General there was a substantial increase in the enforcement of federal human subject protection requirements and federally funded research was suspended at several prominent research institutions because of IRB-related deficiencies. The claim in *the Chronicle of Higher Education* that social science research was not an issue in any of these suspensions is inaccurate. Federally funded research at Virginia Commonwealth University was suspended in January 2000 because its IRB had not adequately protected the subjects of a social science study (a lengthy survey of the health of twins and their families).

A year ago, Midwest Bioethics Center established a consortium for IRBs. The consortium presently consists of thirty-one Kansas and Missouri IRBs. They are a diverse lot. Some serve biomedical research institutions for which human subjects research is central to the mission. Some serve community hospitals for which human subjects research is primarily a medical staff accommodation. Some review a single type of study, for example, oncology. Some are freestanding, for-profit enterprises. The annual volume of initial reviews ranges among the IRB Consortium members from several to several thousand. The institutional support for the member IRBs appears to be increasing rapidly; however, the levels of support vary widely. I suspect the sufficiency of institutional support also varies widely. Four campus-based IRBs review only social science studies.

If the IRB Consortium members fairly represent the larger community of IRBs, the mission of protecting human research subjects may be the only common denominator of this diverse world. Given the pattern of variety among IRBs, *The Chronicle of Higher Education* article's claim that there are fundamental differences between social science and health science research is beyond dispute. Identifying these differences and deciding how they should inform IRB practice is important work. The principle of justice, that we ought to treat like cases alike and different cases differently, should help us respond to the unique issues of protecting the human subjects of social sciences research. On the other hand inaccurate claims like that reported in *the Chronicle of Higher Education* aren't very helpful. Health science investigators who dismiss social science studies as not "real" research aren't much help either. Identifying these differences and deciding how they should inform IRB practice is important work. The principle of justice, that we

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The following are salient qualities of social science research that should be part of the calculus used by anyone seeking to perfect the role of IRBs as protectors of the human subjects of social science research.

The members of these IRBs explicity understand that, in addition to protecting human research subjects, they are helping student investigators learn the basics of human-subject research.

- Social science research is dynamic. Social science investigators employ a variety of qualitative research techniques, and new research techniques are constantly being developed, validated, and integrated into social science research practice. The IRBs that review social science studies must include social scientists who can evaluate study design from the perspective of these techniques.

  It is understandable that social science investigators would bridle against their studies being reviewed by a committee that doesn't include anyone who appreciates the methodologies that they use. However, we can solve this difficulty by assuring that IRBs have the necessary expertise to make informed reviews. The present schema of reducing the level of protection afforded to the human subjects of less risky research makes sense. Reducing the level of protection based on an assumed relationship between risk and methodology would be a mistake that endangers human research subjects.

- Students do much social science research. Each year thousands of graduate and undergraduate university students conduct social science studies as a step toward completing their degrees. Most of these students are inexperienced investigators. Most of the studies have no financial support. Timelines for developing, implementing, and completing these studies are usually short. The level and sophictication of faculty oversight and support of student research is uneven and sometimes nonexistent.

  I don't know why faculty oversight is so variable, but the variance doesn't reflect the varying levels of risk that the studies represent to their participants. The four social science IRBs that participate in the IRB consortium understand that they have a special responsibility with respect to student research. The members of these IRBs explicity understand that, in addition to protecting human research subjects, they are helping student investigators learn the basics of human-subject research.

  Reducing the level of IRB protection for the subjects of social science research conducted by students would be a mistake for at least two reasons. First, because of their disciplines, some students inevitably do studies that involve vulnerable populations. Some criminal justice students will want to do research that involves prisoners. Some education students will want to do research that involves children. Some nursing students will want to do research that involves people with HIV/AIDS. Second, the subjects of unfunded studies that are

conducted on accelerated timelines by inexperienced investigators who receive uncertain supervision need more IRB protection because the oversight that accompanies sponsorship and peer review is absent.

- Protecting the human subjects of research is more than an IRB responsibility. *The Chronicle of Higher Education* article begins with the story of a masters level university student. The student did an oral history project for his thesis without requesting prior IRB review. After the project was completed, the university's graduate school office noticed the absence of IRB involvement in the project and the student spent two weeks in academic limbo while the university decided what to do. This story raises an important issue that deserves a careful response. Students can innocently fail to seek prior IRB review of their human subject research for many reasons. Most of those reasons reflect a central failing of the way that institutions understand their human subjects protection responsibility.

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Greg Koski is the Director of the federal Office of Human Research Protection. The story of the master's student and his oral history project affirms one of Dr. Koski's primary messages–that protecting human subjects is an institutionwide responsibility.

Here are a few things that might cause a student to fail to seek IRB review:

- The university's assurance letter may not clearly say who may determine that a study is exempt.
- The university may not even have an assurance letter.
- Departmental policies governing student research may be ambiguous.
- The procedure for informing students about their IRB responsibilties may be insufficient. (And whose responsibility is that?)
- Faculty support for the university's human research subject protection program may be weak.
- The student investigator may not have known that he had a fiduciary responsibility to the people who participated in his oral history project.
- The IRB may have made things worse by its response to the information that the project had been conducted without a prior application for IRB review.

This short list of reasons why mistakes like the one described in the *Chronicle of Higher Education* article can happen supports Dr. Koski's argument that protecting human subjects is an institutionwide responsibility.

I believe mistakes like the one involving the master's level student and his oral history project are inevitable in campus settings, even at universities that take human subject protection responsibilities very seriously. The suggestion that we should hedge the prospect of an occasional mistake by reducing the level of protection that we provide to the human subject of studies in which no mistakes occur should not be supported. What we need is a sufficient mechanism for resolving these exceptional cases when they arise.

A sufficient mechanism will have four characteristics: It will be in place before it is needed, not developed in response to the present occurrence of a mistake. It will be part of the institution's human-research subject protection plan. It will resolve cases expeditiously. It will allow the university to craft individual responses to these situations.

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