Reforming IRBs: The Need for a Researcher’s Bill of Rights

Harry Perlstadt, Ph.D., M.P.H.  Professor
Department of Sociology and Institute for Public Policy and Social Research
Michigan State University

Physician and bio-ethicist Howard Brody (Research Integrity 2000) noted that it is important to look at the track record of IRBs and the performance of the research-ethics bureaucracy that has developed since the 1970's. In 1998, the Office of the Inspector General DHHS issued a report Institutional Review Boards: A Time for Reform [June 1998 OEI 01-97-00193]. It unequivocally stated that the effectiveness of IRBs is in jeopardy and proposed the following six reasons for its conclusion: changes in research environment since the 1970's, inefficiencies that result from reviewing too much, too quickly, with too little expertise, conducting minimal continuing review of approved research, facing conflicts that threaten their independence, providing little training for investigators and board members, and not paying much attention to evaluating IRB effectiveness.

Of these six, only the training issue was directly addressed in the intervening years. To be sure some faculty and graduate students still are not familiar with the definitions and general procedures, lack experience in filling out the forms, or fail to attach requested documentation, instruments, cover letters and so forth. The need to better educate researchers to follow accepted ethical principles is important.

But other difficulties are more systemic. In a follow up report in 2000, the Protecting Human Subjects Research: Status of Recommendations [OEI-01-97-00197], the Inspector General repeated the call for IRBs to undergo regular performance-focused evaluations that are carried out in accordance with federal guidelines. Noting how little attention is given to evaluating how successful IRBs were in protecting human subjects, the report states “It is time for the Federal government to mandate self-evaluations, or better yet, evaluations conducted by independent outside parties.” The recent expiration of the National Human Research Protections Advisory Committee ended one avenue though which researchers could influence the Office of Human Research Protections. While some may call for a greater dialog, the IRB
system needs to be reformed and a researcher’s bill of rights is one part of that reform. Rights in the last half of the 20th century have focused on the rights of the weak, the infirm, and the vulnerable to benevolent action from others and protection from harm and injury. The *Belmont Report* uses the term beneficence which it defined as not only protecting human subjects from harm but by making efforts to secure their well being. In terms of research, Thomas Hobbes (*Leviathan* 14) and I contend that researchers have the liberty to protect themselves from attack for the preservation of their own nature, that is, the ability to conduct meaningful, replicable, and valid studies. But as John Rawls (*A Theory of Justice*, 1971) argued, this liberty must be examined within a context of equal basic liberties for all.

The major professional associations recognize that research should be designed and conducted to respect and protect the rights and welfare of human subjects. Many have their own statements on professional ethics and standards regarding (a) risks, harms, and burdens that might be engendered to those participating in research and evaluation, (b) informed consent for participation and (c) informing participants about the scope and limits of confidentiality.

The basic document for human research protections is the 1979 Ethical *Principles and Guidelines for the Protection of Human Subjects of Research*, known as *The Belmont Report*. This report was the end product of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research established by The National Research Act of 1974 (PL 93-348). The eleven member Commission consisted of three physicians, three attorneys, a bio-ethicist, a Christian ethicist, a behavioral-biologist, a physiological-psychologist and the president of the National Council of Negro Women, Inc. Conspicuously missing were any representatives from the main line social science research disciplines or related professional schools such as education, social work or communications/journalism as well as other health professions such as nursing and public health. It is hard to claim that the *Belmont Report* reflects a consensus of researchers.

Given its make-up the Commission differentiated clinical practice from research. It
Reforming IRBs

Harry Perlstadt, Ph.D., M.P.H.          Michigan State University

essentially combined all systematic efforts that involved using individuals to gain information regardless of whether the resulting generalizable knowledge would appear in academic publications, marketing reports, or public opinion polls. The distinction was that research was funded by the federal government should be reviewed, leaving similar but independently or unfunded research free from review.

Further the Commission specifically declined to make any policy determination regarding the problems related to social experimentation because they may differ substantially from those of biomedical and medically related behavioral research. In fact, the Commission declined to make any specific recommendations for administrative action but rather wanted their report to be adopted in its entirety as a policy statement. The Commission, naively it turns out, stated that such problems ought to be addressed by one of its successor bodies.

Almost everyone assumed that the administration of procedures covering the human research projections would be transparent, rational and follow due process. Unfortunately this was a false assumption. It is essential that the human research protection process be fair to both investigators and subjects. The public good is being undermined by the lack of due process and decisions that limit the ability of researchers and evaluators to replicate existing studies using identical methods, conduct unpopular research, and responsibly disseminate findings. The human research protection system is the guardian of the rights of research subjects. But one must ask “Who will guard the guards themselves?”

Over the past decade the Office of Human Research Protections in the US Department of Health and Human Services (OHRP-DHHS) and Institutional Review Boards (IRBs) have tipped the balance between their administrative definitions of what is required to protect human subjects and the ability of researchers and evaluators to collect accurate, valid and replicable information in favor of their administrative powers. One reason may be to limit the legal liability of the IRB and its parent institution.

Although IRBs can authorize a waiver of written consent forms or other formal consent
Reforming IRBs

Harry Perlstadt, Ph.D., M.P.H. Michigan State University

procedures under specified conditions (see 45 CFR Part 46 §116 and 45 CFR Part 46 §117), many are reluctant to do so. Since IRBs have the option of being stricter than the Regulations, disparities are bound to occur within and between IRBs. This threatens the ability of researchers to replicate research permitted by one IRB but banned by their own. The Regulations do not discuss procedures for resolving conflicts between IRBs and researchers. The researcher may appeal the decision, usually to the head of the IRB or an ad hoc committee of IRB members who have not previously reviewed the proposed. Researchers cannot appeal to an outside neutral third party such as a Vice President for Research or a University Committee on Research and Graduate Education. A neutral appeals process is one check and balance in a judicial system.

The National Science Foundation (See www.nsf.gov/bfa/cpo/policy/hsfqs.htm#irb) recommends that if an IRB cannot respond in a way that is helpful, the researcher might consult their scientific society’s code of ethics or discuss the issue with representatives of the scientific society and then provide written documentation of what was learned from them back to the IRB. For example, IRB’s may set higher standards than required by state law for informed consent and release of data. But an arbitrary or capricious IRB decision will stand without access to a neutral appeals process. This is compounded by the failure of the institutions to conduct adequate oversight and independent evaluations of their IRBs. Furthermore the federal government has not required institutions to do so.

The time has come to restore a reasonable balance between the interests of researchers and the powers of IRBs. With encouragement and directives from OHRP, IRBs have expanded their authority over university community members which may abridge First Amendments rights. Some IRB’s require researchers to obtain documented informed consent for asking the very same questions that journalists, market researchers or public opinion pollsters can ask by properly identifying themselves and informing the respondent that answers may be known by millions of people. No effort has been made by OHRP or IRBs to clarify where the constitutional rights of some researcher end and where university power begins. While IRBs
exercise their power in the name of research subjects' interests, researchers have is no protection against the risk that IRBs will develop constraints on inquiry and publication that are responsive to the university's political constituencies and monetary interests.

A Researcher's Bill of Rights is essential. Both universities and scientific professional associations should develop a policy statement addressing the rights of researchers with respect to human research protections. Such a Researcher’s Bill of Rights would include the following provisions:

1) Researchers and evaluators shall have the right to be told of the waivers to documented informed consent contained in 45 CFR 46 and have the waivers considered on the basis of precedent and existing waivers for federal agencies conducting similar research using similar methods on similar subjects.

2) Researchers and evaluators have the right to use data collected by state agencies under human subjects provisions governing those agencies and IRBs cannot set a higher standard than state law or rules nor insist that researchers get documented informed consent from each client.

3) Researchers and evaluators shall have the right to apply federal regulatory criteria that exempt research from IRB review without IRB review of the exemption except insofar as the source of funding specifically requires approval of exemption.

4) Researchers and evaluators shall have the same rights to associate with and observe people, ask questions, and publish the information they acquire as does any person whose rights of assembly, inquiry, and publication are protected by the 1st Amendment of the U.S. Constitution unless the receipt of funding for research specifically requires prior review and approval of research procedures.

5) Researchers and evaluators have the right to fair and uniform procedures and to due process, including having decisions based on precedent and consistent from case to case and from university to university, receiving written reasons for decisions, and the ability
to appeal decisions to a neutral third party.

*Harry Perlstadt is a professor of sociology at Michigan State University. The Researcher’s Bill of Rights was written with the help of Jack Katz, Department of Sociology, University of California-- Los Angeles. It was presented as a motion to the business meeting of the American Sociological Association in August 2002 and was passed on to the ASA Council for its consideration.*