I would like to introduce this topic in two ways. The first is sociological and the second is philosophical. I will then discuss the Belmont Report, which is the basic governing document on Human Research Protections, raise the issue of oversight and evaluation of Institutional Review Boards, and conclude with a declaration and the key concepts of a Researcher’s Bill of Rights.

Sociological Introduction

The sociologist C. Wright Mills (in *The Sociological Imagination*, 1959: 226) wrote that many personal troubles must be understood in terms of public issues and the human meaning of public issues must be revealed by relating them to personal troubles.

I will contend that some of our personal troubles with human research protections and institutional review boards are, in fact, public issues and that the legitimacy of the human research protections system is being jeopardized by the ever growing number of personal troubles. This carries over to whether the person or the social system is blamed for the difficulties.

For example, most of us have difficulties with computer software programming. The learning curve is sometimes steep and we really need to study the manual and work through the help sections in order to gain some degree of mastery. This is a personal trouble and we can assign blame to lack of self education. In some cases, however, the problem is one of communication between the user and the software programmers and companies. Occasionally the manual or the help is not what we term user friendly. The blame may then be shared between the individual user and those who wrote the poorly written instructions. But we also know that some software has major “bugs” in it, design errors that are part of the systems structure and that individual users cannot be expected to circumvent on their own. Here the blame falls on the software programmers and companies, and the remedy is a new point 2 version.

The three criteria that sociologists use to study this situation are the number of people involved, the origins of the problem, and the alternative solutions to the problem. I will contend that a significant number of researchers have problems with human research protections that are structural or systemic in nature and that can only be resolved at the federal government level.

As Howard Brody (2000) noted, 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. But it is also evident that the communications from IRBs are not as clear as they could be. While the MSU UCRIHS website goes into great detail on the elements of informed consent, it does not have a model letter or set of letters that incorporate these elements. Therefore faculty and graduate students often receive memos “suggesting” (and I put that in quotes) that their informed consent include phrases like “if you wish to withdraw from the interview, you
may do so at any time” or “the interview will be tape recorded to insure that it is acceptable TO YOU [caps in original] in order to insure... “ Other universities such as UT Austin have set of letters on their website which researchers can use as a model.

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.”

Philosophical Introduction

Now I would like to redo the introduction from a philosophy perspective. Philosophers have categorized rights into positive and negative rights. Positive rights are rights to benevolent action from others such as food, shelter, or help in an accident. Negative rights are rights to non interference and are subdivided into passive rights, the right to be let alone or not to be injured and active rights, that is the liberty to do as one chooses. For the most part, rights in the last half of the 20th century seem to have focused on positive rights: the rights of the weak, the infirm, and the vulnerable to benevolent action from others. This is somewhat complemented by negative passive rights not to be injured.

The Bellevue 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. The first, do not harm, which derives from the Hippocratic Oath, is clearly a negative passive right. This is complemented by the second positive right to benevolent action operationalized in the Bellevue Report as to maximize possible benefits and minimize possible harms.

Negative active rights, that is, the liberty to do as one chooses is much more problematic. For example, the animal rights movement can be classified as one appealing for positive rights for animals to receive food, shelter and “humane” treatment and the negative passive right not to be injured particularly in the performance of entertainment stunts. The New Yorker (10/07/02 p 69) recently provided examples of animal rights that are negative and active: Animals have the right to drop out of school, hang around trees, track mud everywhere, stay up all night drinking and making noise and to hunt without a license. Clearly animals in the wild, that is, a state of nature, freely exercise these negative active rights, but we expect animals in human society not to poop on our lawns or howl all night.

In terms of research, Thomas Hobbes (Lev 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. This liberty is categorized as a negative active right and therefore must be examined within a context of social justice. John Rawls (A Theory of Justice, 1971) wrote that each person should have an equal right to the most extensive total system of equal basic liberties compatible with a similar system for all. This suggests that negative active rights are not absolute. But I do not take this to mean that certain groups of people have no rights, cannot claim what are considered to be universal rights in their society, or cannot make claims for reasonable and just negative active rights.

The major social science professional associations recognize that research and evaluations 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. They generally refer to the Bellevue Report and federal regulations about protection of human subjects.

The Belmont Report

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 Bellevue Report. The document distinguished between research and practice, identified basic ethical principles applicable to research on human subjects, and called for the
application of these principles as requirements for informed consent, assessment of risks and benefits, and selection of subjects. 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 that conduct research such as education, public health or communications/journalism.

The Belmont Report defined practice as interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. The Commission held that although some forms of practice may benefit some other person, it was designed to enhance the well-being of a particular individual or groups of individuals and need not be reviewed as research. Research was then defined as an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge. It noted that research usually involved the scientific method, that is, a set of procedures designed to reach that objective. The conclusion was that if an activity contained any elements of research, then that activity should undergo review for the protection of human subjects.

This was an all-encompassing definition of research and, given the make-up of the Commission, reflected their primary interest to differentiate clinical practice from research. The Commission 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.

Given its lack of representation from the mainline social and behavioral sciences and professions, 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. Such social experimentation research would include needs assessments, quality improvement studies, and program evaluation among others. They also did not consider epidemiological research or the use of vital statistics in public health. 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.

The Belmont Report was issued in April 1979 and before the end of the year, the National Research Act was amended to include the report’s blunt practice/research distinction. Furthermore, the report’s failure to deal with the specifics meant that all research efforts—biomedical, behavioral, and social—were essentially treated alike when it came to writing the legislation and the regulations. The Act was amended in 1985 and again in 1991 when the Health and Human Services core regulations concerning IRBs and protection of human subjects found at 45 CFR 46 became the Common Rule covering 17 Federal agencies.

The general interpretation is that all research funded by the federal government or conducted by those working in universities or health care settings must be submitted to an Institutional Review Board (IRB) for its review and approval. Furthermore, the Health Resources and Services Administration (HRSA) was able to do what the Belmont Report did not do regarding social experimentation research. Although practically all research activity of the (HRSA) consists of program evaluation or evaluation of demonstration projects which are technically exempt under the public “benefit and service” criterion, HRSA requires such a claim of exemption to be approved by the HRSA Human Subjects Committee, otherwise IRB oversight is required.

IRB Oversight and Evaluation

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 two major rights of research subjects: the negative passive right not to be harmed and the positive right to benevolent action in terms of maximizing possible benefits while minimizing possible harms. Plato wrote that a guardian in training should be the last to get drunk and not know where in the world he is so that the idea that “a guardian should require another guardian to take care of him is ridiculous indeed!” (Republic III 403-E). But in Rome the Praetorian Guard was quite another matter, and the Roman satirist Decimus Junius Juvenal asked “Who will guard the guards themselves?” (Satires VI 1347)

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. The obvious reason was to limit the legal liability of the IRB rather than the protection of human subjects or the conducting of sound research and evaluations. Two examples should suffice.

(1) IRB’s require researchers and evaluators to obtain prior approval and 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 become part of a public record or report. Similar problems arise for researchers or evaluators observing public behavior that is often videotaped or photographed by the media and broadcast to hundreds of thousands world wide.

(2) State law may permit verbal consent to receive treatment and contain provisions for the release of aggregate data for research and/or evaluation purposes with proper confidentiality provisions. This information is contained in a booklet given to all clients receiving state services. But IRBs have the power to hold researchers and evaluators to higher standards of written documented release forms from every client which, if obtained, would violate the very confidentiality assured by the state law.

Although IRBs can authorize a waiver of written consent forms or other formal consent 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/hsfaqs.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. But without access to a neutral appeals process, this is essentially an ineffective suggestion. This is compounded by the failure of the institutions to conduct adequate oversight and independent evaluations of their IRBs. Furthermore, as noted earlier, the federal government has not required institutions to do so.

The Researcher’s Bill of Rights

The time has come to restore a reasonable balance between the interests of researchers and the powers of IRBs. The purpose of federal policy for the protection of human subjects is to protect potential subjects from harm by allowing them to make informed decisions about the risks of participating in a research project. This policy is implemented through a set of independent Institutional Review Boards (IRBs) which interpret and enforce federal regulations at 45 CFR 46.

With encouragement and directives from OHRP, IRBs have expanded their authority over university community members, which may abridge First Amendments rights of peaceful assembly, speech and the press
(which undoubtedly include oral presentation and publication of scientific knowledge and applications). 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, there 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.

The Belmont Report noted that research usually involves the scientific method, that is, a set of procedures designed to reach that objective. The general rule was that research, defined as activity designed to test a hypothesis, permit conclusions to be drawn and to contribute to generalizable knowledge, should undergo review for the protection of human subjects. But the procedures in social research inquiries are commonly no different from ways of associating with people, inquiring about their lives, and writing about society that do not require prior review and possible censorship. This is true for a wide variety of social research from phone surveys and focus groups in corporate market research and political campaigns to ethnographic and other qualitative forms of research, which frequently merge with journalism. The First Amendment does not speak of "journalism" and makes no exception for "research" in the liberties it guarantees. The human research protections system has evolved without regard for constitutionally protected forms of assembly, speech and publication, creating a chilling effect on academic freedom and legitimate scientific inquiry.

The very indifference of OHRP and IRB administrators to the political values they threaten indicates the gravity of the situation. Given the diversity and multiplicity of universities in the U.S., it is inevitable that, without strong protections, some IRBs will use “the interest of research subjects” as a guise for restricting research that is not injurious to subjects but that is offensive to social and political constituencies deemed crucial to the university’s institutional well-being. Such institutional conflicts of interests should not apply when determining claims that a given form of inquiry should be modified or restricted because of the danger it poses to subjects.

Unfortunately the human research protections review process yields decisions that are inconsistent within and across IRBs. An example of within IRB inconsistencies is that one researcher was allowed to advertise a $25 payment for participation on a campus flier but another researcher was explicitly told not to put any payment amount on the flier. An example of across IRB inconsistencies is that the Centers for Disease Control have received a waiver enabling them to use “passive consent” whereby students and youth will receive the CDC Youth Behavior Risk Survey unless parents or guardians say no but most IRBs will not grant such a waiver for similar or even identical surveys and the Office for Human Research Protections insists that “passive consent” is not permissible. In most cases any appeal of such decisions is internal to the IRB, with no oversight or review by other faculty committees or university officials.

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 become part of a public record or report. Similar problems arise for researchers observing public behavior that is often videotaped or photographed by the media.

In addition, IRB’s may set higher standards than required by state law. For example, if a state law permits verbal consent to receive treatment and has provisions for the release of aggregate data with proper confidentiality provisions, it not only seems unfair, but an override of state law for IRBs to require a researcher to contact every patient and only use the data from those who sign release forms.

Finally, it is not the intent of federal policy to prevent lousy research. It is to prevent harmful research. This important distinction is often overlooked in an attempt to shield subjects from what is defined as poor or unnecessary research.

A Researcher’s Bill of Rights is essential. In addition to whatever conflicts of interest may exist for researchers vis-à-vis research subjects, the conflicts of interest that exist for IRBs by virtue of their institutional location must be taken into account. The proper framework for thinking about these issues is not the simple triad of researcher, research subject, and IRB but the five party framework that adds the university’s various institutional interests and the American constitutional tradition to the mix. The professional associations of social researchers must begin to counterbalance the institutional interests of universities.
This suggests that both Universities and 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.

NOTE: The final section entitled 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.