

The Researcher's Bill of Rights

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The time has come to restore a reasonable balance between the interests of researchers and the powers of Institutional Review Boards (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 IRBs composed of faculty and community members with the unfettered power to interpret and enforce the federal regulations at 45 CFR 46.

With encouragement and directives from the Office of Human Research Protections (OHRP), IRBs have expanded their authority over university community members and thereby may abridge First Amendment 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 researchers end and where university powers begin. 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 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 inconsistencies within IRB 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 dictate acceptable methodologies or 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.¹ In addition to whatever conflicts of interest may exist for researchers vis-a-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 one that includes the university’s various institutional interests and the American constitutional tradition of rights and due process. The disciplinary and professional associations of scholars and researchers must begin to counterbalance the institutional interests of universities.

This suggests that both Universities and disciplinary 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 additional documented informed consent from each client if the agency has already obtained it.

3) Researchers and evaluators shall have the right to claim their research is exempt from IRB review under existing federal regulatory criteria except insofar as the source of funding specifically requires IRB approval of the 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 First 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.

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Notes:

1 The Researcher's Bill of Rights was created with the help of Jack Katz, Department of Sociology, University of California— Los Angeles.