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(<http://www.aaup.org/AAUP/pubsresearch/academe/2006/SO/Reports/ResearchonHumanSubjects.htm>)

Report: Research on Human Subjects: Academic Freedom and the Institutional Review Board

The report that follows, prepared by a subcommittee of the Association's Committee A on Academic Freedom and Tenure, was approved for publication by Committee A at its meeting in June 2006. The report takes issue with aspects of the federal government's regulations for research on human subjects that constitute a threat to academic freedom. The application of the federal regulations to research methodologies that present no serious risk of harm to research subjects has long been of concern to Committee A, which will continue to keep this matter and other troubling features of the regulations on its agenda. Committee A welcomes comments on the report from Association members and other interested parties and organizations. They should be addressed to Jonathan Knight at the Washington office

Research on human subjects conducted by college and university personnel has been governed by federal regulations since the 1960s. Revisions in the regulations have been made over the years; the most recent version was published on June 23, 2005.¹

What has been a constant since the outset is the requirement that—with a few exemptions—all research on human subjects conducted at, or sponsored by, colleges, universities, hospitals, and nonprofit organizations that is to be supported by any of the federal departments and agencies that have adopted the regulations must be approved in advance by a local Institutional Review Board (IRB).²

A second requirement is currently in place, namely, that institutions at which, or under whose auspices, federally funded research on human subjects is to be conducted must provide assurance that they will protect the rights and welfare of the human subjects of all their research on human subjects, whatever its source of funding. This assurance must be approved by the federal Office of Human Research Protections. For a variety of reasons, which we will return to, most academic institutions have adopted the same protection for subjects of research that is not federally funded as for subjects of federally funded research, that is, they require advance approval of the research by an IRB.

Those requirements have generated an increasing number of complaints over the years, and there is a by now enormous literature that points to their objectionable features.³ In section one, we draw attention to some of the complaints. In sections two and three, we make two recommendations, one to policy makers, the other to academic institutions. In section four, we make a recommendation to the AAUP.

1. Some Complaints

Under the IRB review procedure, an investigator must obtain prior IRB approval of his or her research protocol before the research can be undertaken.⁴ Members of a campus IRB are instructed by the regulations to decide, among other things, whether the risks the

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research would impose on its “subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”⁵ Thus IRB members are instructed to form their own view of the risks their colleagues’ research would impose on its subjects, and on the importance of the results that might be obtained from the research, and to deny permission to conduct the research if in their view the risks are not reasonable relative to the value of the likely results. There could hardly be a more obvious potential threat to academic freedom.

Moreover, no provision is made in the regulations for an appeal process in case a research protocol is rejected by a campus IRB. It is consistent with the regulations for an institution to provide an appeal process, but where the research is to be federally funded, or the institution has opted for a single review procedure that requires IRB approval, the appeal process would have to be to yet another IRB. We do not in fact know of any institution that makes explicit formal provision for such an appeal.

Lack of an appeal process is relevant in another way. An IRB may demand that a change be made in a research protocol as a condition of approval. Prospective researchers are given an opportunity to try to convince the IRB that the change need not be made, but scheduling difficulties often cause lengthy delays; and in any case, unless the prospective researcher is able to convince the IRB to rescind its demand, the IRB’s demand settles the matter.

This unchecked power granted to IRBs has resulted in a number of more or less familiar horror stories. We mention only a few:

- A linguist seeking to study language development in a preliterate tribe was instructed by the IRB to have the subjects read and sign a consent form before the study could proceed.
- A political scientist who had bought a list of appropriate names for a survey of voting behavior was required by the IRB to get written informed consent from the subjects before mailing them the survey.
- A Caucasian PhD student, seeking to study career expectations in relation to ethnicity, was told by the IRB that African American PhD students could not be interviewed because it might be traumatic for them to be interviewed by the student.
- An experimental economist seeking to do a study of betting choices in college seniors was held up for many months while the IRB considered and reconsidered the risks inherent in the study.
- An IRB attempted to block publication of an English professor’s essay that drew on anecdotal information provided by students about their personal experiences with violence because the students, though not identified by name in the essay, might be distressed by reading the essay.
- A campus IRB attempted to deny an MA student her diploma because she did not obtain IRB approval for calling newspaper executives to ask for copies of printed material generally available to the public.

We selected those examples from experiences of prospective researchers in a variety of different disciplines in the social sciences and humanities. Here is an example drawn from the experience of

those who sought to conduct a multicenter observational study of medical treatment for substance abuse:

- Nearly eighteen months and 17 percent of the total research budget had to be spent on obtaining the nine IRB approvals that were required for the study to be undertaken. The IRBs demanded many changes in the formatting and wording of the consent and survey forms, and each change demanded by one IRB had to be approved by all the others. The researchers claim that by the end of the process, no substantial change had been made in the protocol, and that the changes demanded had no discernible impact on the protection of human subjects.⁶

2. Recommendation to Policy Makers

Federal regulation of research on human subjects was a response to public and legislative concerns about lack of oversight of biomedical research, fueled in large part by publicity about the Public Health Service's study of syphilis in Tuskegee, Alabama. It is arguable that the IRB system that was developed over the years has been effective in protecting the subjects of biomedical research that would otherwise impose a serious risk of harm on them. While we know of no empirical research on the benefits of the system, it is arguable that it has institutionalized awareness of the fact that research on human subjects can raise morally significant issues.

What is deeply troublesome is the fact that research on human subjects must obtain IRB approval whether or not it imposes a serious risk of harm on its subjects.

A number of commentators have recommended that the regulations be revised so as to exempt research in the social sciences and humanities, leaving the IRB system to govern all biomedical research and only biomedical research. We believe that recommendation to be a mistake, on two counts. (1) It is arguable that some social science research has the potential to cause serious psychological harm. An example that generated public anger, and that has come in for much discussion since, is the experiment conducted by Stanley Milgram at Yale in the early 1960s. (In that experiment, the subjects were ordered to do what they were falsely told would cause pain to others as part of a study of learning; the aim of the experiment was to find out how many of the subjects would obey the orders.) We do not address this argument here. We point to it merely in order to bring out that an across-the-board exemption for all social science research is arguably overbroad. (2) Some biomedical research does not impose a serious risk of harm on its subjects—for example, biomedical research that involves no bodily interventions and consists entirely of an effort to acquire survey data.

It is our view, therefore, that a markedly better revision would address itself not to the discipline of the researcher, but rather to the method by which the projected research would be conducted. In particular, we recommend that research whose methodology consists entirely of collecting data by surveys, conducting interviews, or observing behavior in public places be exempt from the requirement of IRB review.

Research conducted by those methodologies is explicitly exempted by the regulations—but with an important proviso, namely, that the

research is exempt 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.⁷ And a request for exemption from IRB approval has itself to be approved by an IRB.

The concern expressed in the proviso is not that the projected research might itself harm its subjects; rather, it is a concern about the possibility of breach of confidentiality in respect of the data obtained during the course of the research. Confidentiality in respect to research data is certainly of great importance. But we think that this concern is entirely met by long-standing departmental and disciplinary practices for collecting and storing data. We see no reason for believing that IRB members are better equipped to assess practices for handling data in a discipline than members of the discipline are, and we therefore see no reason for believing that additional oversight by an IRB is necessary.

We add that we can see no even relatively bright line between cases in which a breach of confidentiality might be damaging to the subjects' reputation and cases in which it would not be, given the immense variety of considerations on which a person's reputation rests in one or another community that he or she is a member of. It is no surprise, therefore, that risk-averse administrators, out of a concern about potential lawsuits, have interpreted clause (ii) very broadly, and research whose subjects might be placed at risk of any dismay at all by a breach of confidentiality has been swept into the ambit of the campus IRB.

That this has happened is demonstrated not merely by the breadth of the research methodologies for which IRB approval has been demanded, but also by the fact that the IRBs into whose ambit the research has been swept have demanded details about all of the questions the subjects would be asked in interviews and surveys. Indeed, IRBs have objected to research protocols on the ground that the subjects might find it distressing even to be asked the questions the researcher wishes to ask them. We regard that as an unpardonable piece of paternalism where the subjects are adults who are free to end their participation at any time, or to refuse to participate at all.

Not all research on human subjects is research on adults who can freely make those decisions, of course. Much human subject research is on children; some is research on people who are susceptible to coercion, such as soldiers, prisoners, or the physically or mentally infirm. How those populations are to be protected, and in particular, whether an IRB review procedure is suitable in their case, is a question that we do not address. What concerns us here is only research on autonomous adults.

So in sum, what we recommend is, more precisely, that research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no

requirement of IRB approval of the exemption. We believe that making this change in the regulations would eliminate a considerable amount of the hardship that they have imposed on researchers. Moreover, it would eliminate a considerable amount of totally unnecessary work currently done by IRBs, freeing them to devote attention to seriously risk-imposing research projects.

3. Recommendation to Academic Institutions

Our second recommendation is addressed to colleges and universities. As we said at the outset, institutions at which, or under whose auspices, federally funded research on human subjects is to be conducted must provide assurance that they will protect the rights and welfare of the human subjects of all their research on human subjects, whatever its source of funding.

The question how they are to deal with research that is not federally funded is decidedly not trivial: a considerable amount of research on human subjects that is conducted at, or sponsored by, academic institutions is not federally funded. For example, a recent article reports that nearly 80 percent of all research projects reviewed by the University of Chicago's Social Science IRB are personally funded, privately funded, or unfunded.⁸

As we said, however, most academic institutions have adopted the same protection for subjects of research that is not federally funded as for subjects of federally funded research—that is, they require advance approval of the research by an IRB. The regulations do not require them to take this step; there seem to be three reasons for their doing so.

1. The regulations do not themselves supply clear guidelines as to what alternative institutional arrangements might be regarded as acceptable. The regulations say only that the institution's assurance must include

a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself.⁹

The form that institutions are currently required to submit to the federal Office of Human Research Protections, called the Federalwide Assurance, is slightly, but not much more informative:

All of the Institution's human subjects research activities, regardless of whether the research is subject to federal regulations, will be guided by the ethical principles in: (a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, or (b) other appropriate ethical standards recognized by federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects.

As for (a), the Belmont Report can be found at

<http://ohsr.od.nih.gov/guidelines/belmont.html>. What is envisaged under (b) is presumably whatever ethical standards led the federal departments and agencies that have adopted the requirement of an IRB system to adopt that requirement, and thus (b) offers no help to the institution that is interested in developing an alternative.

2. In order to argue that an alternative would adequately protect the rights and welfare of the subjects of research that is not federally funded, the institution has to be ready to argue also that the IRB system is not morally necessary for protecting the rights and welfare of the subjects of federally funded research. (For it can hardly be thought that the rights and welfare of human subjects wax and wane in moral importance according to the source of the funding of the research to be done on them). Producing such an argument requires a willingness to swim upstream that is not exactly common in academic administrators.¹⁰

3. Academic administrators are risk averse and are likely to have thought that any apparent weakening of the constraints under which their research on human subjects is conducted might subject them to lawsuits they would otherwise be safe against.

All the same, we strongly recommend that colleges and universities take the opportunity that the regulations make available to them and formulate a separate set of procedures for research that is not federally funded.¹¹

Federal regulation of federally funded research on human subjects issued from concern about what was perceived as unacceptable research, such as that conducted in Tuskegee, Alabama; the regulations that were developed display their source—they are concerned entirely with protecting the subjects and give no weight at all to the academic freedom of researchers or to what the nation may lose when research is delayed, tampered with, or blocked by heavy-handed IRBs. An effort should therefore be made to find an alternative that is sensitive to those values as well as to the rights and welfare of the human subjects.

Some institutions have evidently decided to make the effort: to date, 164 have explicitly declined to commit themselves to imposing on research that is not federally funded the regulations that govern federally funded research, including Harvard and Princeton Universities, the University of Chicago, and the University of California, Berkeley.¹² We do not know what procedures they have adopted to govern research that is not federally funded; we recommend that that information be obtained and published.

Our impression at the moment, however, is that many of those institutions continue in practice to impose the same requirements on research that is not federally funded as on federally funded research—perhaps out of lack as yet of an agreed-upon alternative, perhaps because their faculties are not even aware that their administrations have taken this step, or that adopting an alternative is so much as possible, and have therefore brought no pressure to bear on their administrations to try to construct one.

We do not here recommend alternatives to imposing the requirement of IRB approval on research that is not federally funded. Schools might consider an alternative under which the approval required is limited to approval by the researcher's department or other

appropriate academic unit; this is arguably suitable at least for student research—students do a considerable amount of the social science research conducted by academic personnel. Or they might consider a revised version of the IRB system mandated for federally funded research. There surely are other possibilities—information from the 164 schools that have decided to go their own way would be very helpful. We stress only that whatever procedure is adopted, the schools should exempt research that proceeds by way of the methodologies we discussed in section two, whatever its source of funding.

4. Recommendation to the AAUP

As we said above, there is a by-now enormous literature that points to objectionable features of the federal regulations governing research on human subjects. Some minor revisions have been made over the years; what are the prospects for a major revision? In particular, what are the prospects for a revision of the kind we recommended in section two above?

As things stand, they aren't very good. Any significant revision of the regulations requires approval by most of the federal departments and agencies that have adopted them—and there are by now seventeen.¹³

Discussion and negotiation among those departments and agencies regarding potential changes to the regulations are handled by an interagency group called the Human Subjects Research Subcommittee, which passes on a recommendation to its parent committee, the Committee on Science. The Committee on Science—which is under the auspices of the Office of Science and Technology Policy, which is part of the Executive Office of the President—usually moves fairly rapidly when it receives a recommendation for change: it gets the recommendation into the Federal Register for public comment as soon as possible. Most of the delay in the process is caused at the initial stage, since it can take a long time for seventeen departments and agencies to come to agreement, and the more controversial or sweeping the proposed change, the longer it can take. While in some cases, a change has been made within a few months, in others the process has taken ten years.¹⁴ It is also possible for the regulations to be changed by legislation. But this process is also often very slow. In any case, we know of no pressure currently being brought to bear in support of legislative action.

We have no view about which procedure it would be best to adopt for obtaining a change in the regulations. Whichever the procedure, however, a considerable amount of publicity and pressure is required if any attempt at obtaining a change is to have a chance of success.

Many organizations are in a position to contribute to generating that publicity and pressure: the disciplinary associations and the national associations such as the American Council on Education, the Association of American Universities, and the AAUP have a commendable record of support for freedom of inquiry through legislative and regulatory intervention.

It is our view that the AAUP—as representative of faculty members across disciplines—is uniquely well placed to serve as coordinator.

We recommend that the AAUP invite representatives of those and other relevant organizations to a conference to consider the possibilities for joint action.

For it cannot be strongly enough stressed that unless a focused strategy is adopted, and concrete steps taken, nothing will change. Indeed, it is possible that the requirement of advance IRB approval of research will come to be imposed even more broadly than it currently is. Complaints published here and there over the years have accomplished little beyond generating an angry and deeply dismaying literature. "

JUDITH JARVIS THOMSON (Philosophy), Massachusetts Institute of Technology, *chair*

CATHERINE ELGIN (Philosophy), Harvard Graduate School of Education

DAVID A. HYMAN (Law and Medicine), University of Illinois at Urbana-Champaign

PHILIP E. RUBIN (Surgery), Yale University School of Medicine and Haskins Laboratories

JONATHAN KNIGHT, Association staff

Notes:

1. It can be found at

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.

2. For a list of the federal departments and agencies that have adopted the regulations, see footnote 13 below. We discuss one of the exemptions in section two. The others include research in "established or commonly accepted educational settings, involving normal educational practices," research on people who are "elected or appointed public officials or candidates for public office," research on materials that are publicly available, and research designed to assess "public benefit or service programs." The entire list of exemptions may be found at sec. 46.101(b) of the federal regulations on IRBs (see footnote 1).

3. Some references may be found in what has come to be called the Illinois White Paper, namely, "Improving the System for Protecting Human Subjects: Counteracting IRB 'Mission Creep,'" available at <http://www.law.uiuc.edu/conferences/whitepaper/>. The AAUP has itself published two reports on these matters: a subcommittee report entitled "*Regulations Governing Research on Human Subjects*" in the December 1981 issue of *Academe* and a staff report entitled "*Protecting Human Beings: Institutional Review Boards and Social Science Research*" in the May-June 2001 issue.

4. A recent article argues that federal imposition of this requirement is unconstitutional. See Philip Hamburger, "The New Censorship: Institutional Review Boards," *Supreme Court Review* 271 (2004): 271-354. We take no stand on the merits of the author's argument.

5. See sec. 46.111 (a)(2) of the federal regulations.

6. See Keith Humphreys et al., Letter to the Editor, *Annals of Internal Medicine* 139 (2003): 77, and Michelle L. Brandt, "IRB Burden Studied in Cost Analysis," *Stanford Report*, August 6, 2003. It is surprising, given the fact that the current system of regulations has been in force for so many years, and the vehemence of the

published objections to it, that hardly any empirical research has been undertaken to assess its costs—and none at all to assess its benefits.

7. See sec. 46.101 (b)(2) of the federal regulations.

8. See Richard A. Schweder, “Protecting Human Subjects and Preserving Academic Freedom: Prospects at the University of Chicago,” *American Ethnologist* 33, no. 4 (2006): forthcoming.

9. See sec. 46.103 (b)(1) of the federal regulations.

10. The way upstream would be markedly more difficult for an academic administrator who argued, more aggressively, that academic institutions should not be held responsible for protecting the rights and welfare of any of their human research subjects, however the research is funded—markedly more difficult because regulation 46.103 (b)(1), which we quoted just above, explicitly declares that institutions do have “responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.”

11. While we have no hard evidence on the matter, it is our impression that institutions’ fear of lawsuits if they decline to require IRB approval for research that is not federally funded is not warranted by experience.

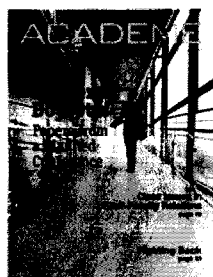
12. This information was provided by the U.S. Department of Health and Human Services in response to a Freedom of Information Act request submitted by the AAUP. For the names of other institutions, contact Jonathan Knight in the AAUP’s Washington office.

13. The seventeen are Agency for International Development, Central Intelligence Agency, Consumer Product Safety Commission, Department of Agriculture, Department of Commerce, Department of Defense, Department of Education, Department of Energy, Department of Health and Human Services, Department of Housing and Urban Development, Department of Justice, Department of Transportation, Department of Veterans Affairs, Environmental Protection Agency, National Aeronautics and Space Administration, National Science Foundation, and Social Security Administration.

14. It is possible for changes to be made in the regulations even if not all the departments and agencies agree to them. However, there are strong norms of uniformity at work on them, which helps to explain why delays are common—while unanimity is not always reached, efforts are made to try to reach it.

American Association of University Professors
1012 Fourteenth Street, NW, Suite #500; Washington, DC 20005
Phone: 202-737-5900 | Fax: 202-737-5526

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