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

(MARCH 2013)

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 2012.

Funding of research on human subjects by the federal government grew dramatically during the last century. In 2010, the government spent over $16.5 billion on extramural research on human subjects, that is, research on human subjects conducted at colleges, universities, and other nongovernmental institutions, such as hospitals. It also spent a considerable sum on intramural research on human subjects, that is, research on human subjects conducted directly by government personnel at government facilities.[1] Most of the money supported biomedical research; the rest supported research in the behavioral and social sciences.

Not surprisingly, elaborate peer-review systems were developed over the years for assessing the scientific value of the applicants' research projects. In light of the unethical research that had been conducted or funded by the Public Health Service—such as the Tuskegee Syphilis Study and a cancer study at the Jewish Chronic Disease Hospital in Brooklyn—policy makers decided that recipients of federal funds for research must adhere to certain moral standards in conducting their research.[2]

Rather than require that those standards be enforced directly by a central office, policy makers chose to require that they be enforced locally: researchers were to demonstrate the ethical acceptability of their projects to a representative local board, an institutional review board (IRB) at the institution under whose auspices the research would be conducted.

Under the current regulations, an IRB must have at least five members—most IRBs currently have more—who are qualified by their experience and expertise to assess scientific research and who are diverse in various ways, including race and gender. Moreover, the primary concerns of at least one member must be in a science, those of at least one member must be in a nonscientific discipline, and at least one member must be otherwise unaffiliated with the institution.

1. *Moral Science: Protecting Participants in Human Subjects Research,* Report of the Presidential Commission for the Study of Bioethical Issues, December 2011.

2. The research at the Tuskegee Institute is well known. A recent description is Susan Reverby's *Examining Tuskegee* (Chapel Hill: University of North Carolina Press, 2009). The research at the Jewish Chronic Disease Hospital is perhaps less well known. In that study, undertaken in mid-1963, the researchers "injected live cancer cells into indigent elderly patients without their consent. The research went forward without review by the hospital's research committee and over the objections of three physicians consulted, who argued that the proposed subjects were incapable of giving adequate consent to participate" (*Report of the Advisory Committee on Human Radiation Experiments,* part 1, chap. 3, http://www.hss.doe.gov/healthsafety/ohre/roadmap/achre/chap3_2.html). The report summarizes the effect of revelations of research malpractice on the formation of national policy.

The ethical standards that IRB members are to employ in assessing research projects are based on the ethical principles described in the 1979 Belmont Report: in *very* brief summary, IRB members are to bring to bear in their assessment of research projects appropriate principles of respect for persons, beneficence, and justice. (According to the Belmont Report, the requirement of informed consent by research subjects is an application of the principle of respect for persons.) With the exception of a few types of research—they are listed in the regulations—research on human subjects will be funded by the federal government only if it obtains IRB approval. The IRB is then to conduct continuing, at least yearly, review of all ongoing research that it has already approved. The body of rules just summarized is often called the Common Rule.[3]

Typically, applicants for extramural federal funds for research on human subjects do not apply for such funds independently: their institution applies for them, and it is to their institution that the funds are disbursed. In applying for the applicant, the institution certifies the details of the project's budget, including information about the institution's "overhead" (its charge for the use of its facilities), and gives assurance that the applicant's project has been approved by the institution's IRB.

Finally, the federal government does not fund any research on human subjects conducted at an institution unless the institution provides an assurance that all nonexempt research on human subjects conducted there, whatever its funding source, meets the moral standards the IRB system was created to enforce. That leaves it open to an institution to construct a different moral certification system for research on human subjects that is not going to be federally funded. However, out of concern about the possibility of lawsuits brought against them by research subjects and because of the importance to them of the funds they obtain from the federally funded research conducted by their personnel, most institutions satisfy this requirement by mandating that all nonexempt research on human subjects conducted under their auspices, whatever its funding source, obtain IRB approval.

Over the years, the regulations have generated increasing numbers of complaints, from researchers in the behavioral and social sciences in particular, but from researchers in the humanities as well. Horror stories abound—for example, of IRBs' demanding inappropriate, indeed absurd, alterations in research protocols, for another example, of IRBs' refusing to approve of research surveys on the ground that their (autonomous adult) subjects might be dismayed or embarrassed by the questions put to them.[4] Biomedical researchers have also complained, charging that the current system inappropriately steers scarce resources toward the review of minimal risk research, produces inconsistent results from one IRB to the next, and imposes a heavy administrative burden.[5]

For these reasons, the Department of Health and Human Services (HHS) published an advance notice of proposed rule making (ANPRM) in the *Federal Register*

3. Strictly speaking, the Common Rule currently governs only eighteen federal departments and agencies, namely, Department of Agriculture, Department of Commerce, Department of Defense, Department of Education, Department of Energy, Department of Health and Human Services, Department of Homeland Security, Department of Housing and Urban Development, Department of Justice, Department of Transportation, Department of Veterans Affairs, Agency for International Development, Consumer Product Safety Commission, Environmental Protection Agency, National Aeronautics and Space Administration, National Science Foundation, Social Security Administration, and Central Intelligence Agency. Not included are, among others, the Library of Congress and the National Endowment for the Humanities. (The Food and Drug Administration applies its own version of IRB standards to research done to obtain marketing approval for drugs and medical devices, whatever the source of its funding.)

In *Moral Science,* the presidential commission recommends that all federal agencies that conduct or support research on human subjects adopt regulations consistent with those that already govern the eighteen.

The Common Rule and the Belmont Report may be found at the website of the government's Office for Human Research Protections (OHRP). Zachary Schrag describes the history of the regulations in *Ethical Imperialism: Institutional Review Boards and the Social Sciences*, 1965–2009 (Baltimore: Johns Hopkins University Press, 2010). See also Laura Stark, *Behind Closed Doors: IRBs and the Making of Ethical Research* (Chicago: University of Chicago Press, 2012).

4. We described some of the horror stories in our 2006 report: see Judith Jarvis Thomson, Catherine Elgin, David A. Hyman, Philip E. Rubin, and Jonathan Knight, "Research on Human Subjects: Academic Freedom and the Institutional Review Board," *Academe,* September–October 2006, 95–100. For more, see Will van den Hoonaard, *The Seduction of Ethics* (Toronto: University of Toronto Press, 2011), and Schrag, *Ethical Imperialism,* 161–72. Some earlier complaints were discussed in our 1981 report: see Judith Jarvis Thomson, Sanford Chodosh, Charles Fried, DeWitt S. Goodman, Murray L. Wax, and James Q. Wilson, "Regulations Governing Research on Human Subjects: Academic Freedom and the Institutional Review Board," *Academe,* December 1981, 358–80.

5. See, for example, Scott Kim, Peter Ubel, and Raymond De Vries, "Pruning the Regulatory Tree," *Nature* 457 (January 29, 2009): 534–35,

on July 26, 2011, inviting responses from the public at large. More than eleven hundred responses were submitted, including a response by the AAUP's staff.[6]

Judging from the ANPRM, we believe that HHS intends to give the regulations a deep reconsideration at this time, and it therefore seems to us that some very general comments would be in order.

1. We begin, however, with a survey of the responses submitted to the ANPRM in order to bring out what has most troubled those who must live under the regulations.

Since researchers in the behavioral and social sciences have most strongly complained about the existing regulations' encroachment on academic freedom, we read (a) all of the responses by all of the major scholarly associations in those disciplines. Since strong complaints have also been made by researchers in the humanities, we also read (b) responses by history, oral history, and folklore associations. We also read (c) an assortment of responses by organizations or consortiums in computer science, database storage and archiving, and general education. In all, our sample consisted of twenty-eight responses.[7]

Several themes reappeared in many of the responses. We list the most important.

a. A very common complaint is that the current list of research types that are exempt from IRB review is far too short. And many organizations expressed objections to the fact that under the current understanding of the regulations, a research project's exemption requires approval by an IRB or by an IRB member or representative.
b. Objections were made to what the organizations regard as inappropriate reporting requirements: for example, the requirement that the protocol of a study to be conducted through interviews must contain a complete list of all of the questions that would be asked during the course of the interviews.
c. Objections were made to what the organizations regard as excessive reporting requirements: for example, the requirement that all procedures to be used in the process of the research be described in detail in advance, the requirement that any change in the procedure by which the research will be carried out be approved in advance of making the change, and the requirement that ongoing approved research must be reviewed by the IRB yearly. Many of those who made objections of this kind objected to what they regard as an absurdly heavy administrative burden that the current regulations impose on researchers and to the delay it causes.
d. Many complained of IRB regulations on consent. Some complained that IRBs often required signed consent forms inappropriately, as, for example, in requiring that researchers obtain signed consent forms from their prospective subjects in advance of mailing them a survey questionnaire. Some complained that researchers are forced to include too much information in consent forms, with the result that research subjects sometimes find them unreadable and either refuse to participate for that reason or participate without paying any serious attention to the consent form's contents.
e. All who mentioned the regulations governing confidentiality of research data expressed dissatisfaction with them. Some complained that the regulations are excessively strict, preventing release of important data the publication of which would cause no harm and excessively

and Lee A. Green, Julie C. Lowery, Christine P. Kowalski, and Leon Wyszewianski, "Impact of Institutional Review Board Practice Variation on Observational Health Services Research," *Health Services Research* 41, no. 1 (February 2006).

6. The ANPRM was published under the title "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," 76 FR 143 (July 26, 2011): 44512–31. The AAUP staff's response (October 12, 2011) may be found at http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0371.

7. The twenty-eight were American Anthropological Association, American Association for Public Opinion Research, American Association of Central Cancer Registries, American Economic Association, American Educational Research Association (on behalf of twenty-two research associations), American Folklore Society, American Historical Association, American Political Science Association, American Psychological Association, American Statistical Association, Association for Computing Machinery, Association of Academic Survey Research Organizations, Association of American Universities, Consortium for Qualitative Research Methods, Council on Governmental Relations, Electronic Frontier Foundation, Institute for Social Research, Inter-University Consortium for Political and Social Research, Joint Policy Committee of the Societies of Epidemiology, Law and Society Association, Linguistic Society of America, National Association of Children's Hospitals, National Association of Veterans' Research and Education Foundations, Oral History Association, Population Association of America, Society for Industrial and Organizational Psychology, Society of American Archivists, and UCLA Social Science Data Archive.

constraining secondary use of data already collected. At the other extreme, some complained that the regulations are inadequately protective of confidential information.

f. The current regulations permit an institution to provide an appeal process for a researcher whose project is rejected, or (as the researcher thinks) gutted, by his or her IRB but do not require that such a process be provided. All of the organizations in our sample that mentioned appeal processes expressed the view that institutions ought to be required to provide an appeal process.

g. The current regulations give institutions the choice of whether to require that research on human subjects that is not federally funded be subject to the same review process as research on human subjects that is federally funded. The ANPRM requests comments on whether this option should be closed—that is, whether HHS should require "domestic institutions that receive some Federal funding from a Common Rule Agency for research with human subjects to extend the Common Rule protections to all research studies conducted at their institution" (76 FR 44528). Some responses in our sample support this proposal; others oppose it.

All of these concerns deserve attention. We can discuss only some, and of them only some at length.

2. We begin with (a), complaints that the current list of exemptions is far too short.[8]

We stop first, however, to draw attention to a quite general feature of the current regulations that emerges on consideration of that list of exemptions. Out of respect for liberty, it is normally expected that government regulation of behavior will consist in listing what is forbidden, all else being permitted. It might therefore have been expected that the federal regulations governing research on human subjects would list the kinds of research that must obtain IRB approval, researchers being free to do research of other types as they think best.[9]

8. According to the current regulations [45 CFR 46.101(b)]:

> Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:
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> (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
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> (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, 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.
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> (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
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> (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
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> (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
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> (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

9. It might be worth mention that some countries, such as Germany and the Netherlands, require ethics reviews only for clinical medical trials, all other research on human subjects being exempt. For Germany, see "National Information: Germany," European Network of Research Ethics Committees, accessed June 18, 2012, http://www.eurecnet.org/information/germany.html. For the Netherlands, see Kingdom of the Netherlands, Research Involving Human Subjects Act as of March 1, 2006, http://www.ccmo-online.nl/hipe/uploads/downloads_catw/Medical%20Research%20involving%20Human%20Subjects%20Act%20March%2001%202006.pdf (accessed June 18, 2012); and Patricia Jaspers, "Controversial Issues in the History of Dutch Research Ethics Governance," *Journal of Policy History* 23 (2011): 74–93. In

That is not the structure of our current regulations. They instead list the kinds of research that is exempt from the requirement of IRB approval, all other types requiring it.[10]

The history of this choice of regulation structure is complex, and we do not summarize it.

In this section, we assume the current regulation structure; that is, we assume that it is exemptions that are to be listed. In short, we believe that those who complain about the current list are right to do so.

In our 2006 report, we focused on a distinction between two ways in which a research project can impose a risk of harm on its subjects.

(i) A research project can impose a risk of harm on its subjects by virtue of its methodology. Thus a research project might require the investigator to give a patient a certain drug or to withhold a drug from a patient who would otherwise have been receiving it. Or a research project might require the investigator only to ask his or her subjects a series of questions. The risk of harm a research project imposes by virtue of its methodology is the risk of harm caused by the researcher's procedure for *obtaining* the data that it is his or her aim to obtain.

(ii) Alternatively, a research project can impose a risk of harm on its subjects by virtue of the possibility that the researcher's procedure for *storing* the data he or she obtains will give the data inadequate protection, the risk of harm being the greater according as the data obtained are the more sensitive and storage of them the less secure.

We said we could see no reason for believing that IRB members are particularly well equipped to assess a project's procedures for storing data and that we could therefore see no reason for believing that research projects that impose risks of harm only in way (ii) call for IRB approval. So we recommended "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 continue to think well of that recommendation. We think we were right to believe that it is in respect of research done on autonomous adults that the exemptions supplied are weakest. We agree that the two different ways in which a research project can impose risks of harm are importantly different and that research that imposes risks of harm only in way (ii) should not be required to obtain IRB approval. And we agree that research whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places should be exempt from the requirement of IRB review, even if it imposes a risk of harm in way (ii).

But we now think that more needs to be said than we said in 2006 about why research that imposes risks of harm only in way (ii) should not be required to obtain IRB approval; we therefore return to that recommendation in section 7 below.

And we now think it clear that the list of methodologies we supplied is inadequate. For example, research that consists entirely in writing to certain distinguished biologists to ask for their views about procedures for teaching about evolution would not be exempt under that formula, yet surely it should be. Similarly for the research in anthropology that proceeds by way of "participant observing" in the course of which the observer interacts with the observed.

One option, then, is to try to find a suitable exhaustive list of exemptions.

A better option is to fix on a general feature, possession of which by a research methodology marks it as belonging on the list. For what is it that those methodologies have in common that marks them as belonging on the list? Choice of methodologies to exempt cannot acceptably be arbitrary; there has to be some general principle that members of the list satisfy, their satisfying the principle being what marks them as belonging on the list. And researchers are entitled to be told what the principle is.

So *why* does it seem right to think that research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places—or analyzing the views of distinguished contemporary biologists about teaching evolution or participant observing in a nonliterate tribe—should be exempt from the requirement of IRB review?

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the United States, federal law (42 USC 289) covers only "biomedical and behavioral research involving human subjects." It might therefore have been expected that US federal regulations would govern human subjects research of only those two categories.

10. See Schrag, *Ethical Imperialism*, and Mark Frankel, "Public Policy-making for Biomedical Research: The Case of Human Experimentation" (PhD dissertation, George Washington University, 1976).

An intuitively plausible answer is that those procedures for obtaining data impose no more than a minimal risk of harm in way (i) on the research subjects. (We postpone until section 5 discussion of the risks of harm they might impose in way [ii], that is, by breach of confidentiality.) It is of course possible that if researchers ask a randomly chosen subject about his voting preferences, they will thereby cause him to drop dead, and thus the researchers impose *some* risk of death on him in asking him the question. However, there is no good reason to believe that that risk is more than minimal.

Nevertheless, it is arguable that interviewing might impose a more than minimal risk of harm on its subjects. For example, a journalist might impose a considerably more than minimal risk of harm on a person by the question he or she asks in the course of the interview—not just by breach of confidentiality after the interview but in the course of conducting the interview in public, perhaps on television. Yet we think it clear, as we did in 2006, that interviewing should be exempt.

There is room for a rebuttal. It might be argued that the journalist of that example does not really impose a risk of harm on the subject, for the researcher does not cause the harm to the subject that ensues, if it ensues. Rather, the journalist merely invites the subject to express opinions on a series of questions, and the subject imposes the risk of harm on himself or herself by choosing to answer the questions as he or she does, indeed, by choosing to answer the particularly difficult questions, or any questions at all. If that is right, then interviewing is a minimal risk research methodology.

We are in considerable sympathy with that rebuttal, but we can leave aside the question whether it succeeds because the claim that interviewing is a minimal risk methodology (even if true) seems to miss what is peculiarly objectionable in requiring that research on autonomous adults whose methodology consists entirely in collecting data by interviews—or indeed by surveys—be approved by an IRB. What is peculiarly objectionable in that requirement is that it interferes with freedom of speech. You do not need to get approval from an appropriately chosen Moral Review Board if you want to invite your neighbor to tell you about his or her voting preferences, or about the teaching of evolution, or about anything else, whether your aim is to do research or merely pass the time while waiting for the bus and whether, given that the conversation is public, your neighbor will have been caused a harm by it. It is no more in order to require researchers to obtain IRB approval before inviting their subjects to discuss or report on their views.

We therefore think it best to recommend a disjunctive condition for exemption, namely:

> Research on autonomous adults should be exempt from IRB approval (straightforwardly exempt, with no provisos and no requirement of IRB approval of the exemption) *if* its methodology either
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> (a) imposes no more than minimal risk of harm on its subjects, or
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> (b) consists entirely in speech or writing, freely engaged in, between subject and researcher.

One of the attractions of that condition for exemption is that its clause (a) sweeps in, and explains why, other kinds of research on autonomous adults than those we have so far mentioned should also be exempt. Consider, for example, the research methodologies that rely wholly on performing routine physical or psychological examinations or tests.

Those methodologies are referred to in the definition of "minimal risk" in the federal regulations: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102[i]). Many commentators have objected to that definition. A common objection is that it is inadequately informative, since people differ widely in the risks they encounter in daily life. (For example, some do and some do not live in risky surroundings.) But the procedures used in routine physical examinations or tests (such as collecting blood, urine, and saliva samples, noninvasive physiological monitoring, and vision and hearing tests) and in routine psychological examinations or tests (such as tests of memory, cognition, and language acquisition and skills) are surely examples of minimal risk methodologies.[11]

11. Those examples of routine physical and psychological examinations and tests come from the list of "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" issued by OHRP and last updated in 1998. That document states that the procedures on its list "should not be deemed to be of minimal risk simply because they are included on this list." We claim that those we listed in the text above *are* minimal risk procedures.

Under the current regulations, expedited review consists in review by the local IRB's representative rather than the IRB's full membership,

But if that definition of minimal risk is inadequately informative, how is the term to be defined? The risk of a harm is easily enough defined: it is the product of the probability of the harm times its gravity. (The gravity of a harm may be expected to increase with the length of time that the harmed person undergoes it.) But what is a minimal risk of a harm? A correct definition, though it is inadequately informative in a different way, is the following: minimal risk of harm means very low risk of harm. We think that the likelihood of finding a correct definition that is informative in the way desired—that is, a definition by appeal to which it can be established that a given methodology is or is not a minimal risk methodology (alternatively, is or is not a very low risk methodology)—is at best vanishingly small.

On the other hand, producing such a definition can hardly be necessary, for the expression is in ordinary use, and it is not by having been given a definition that we learned its meaning in the first place. Indeed, we know enough about what it means to be able to tell when we are offered an incorrect or uninformative definition of it.

We learned what it means by being given examples, and we think it would be useful to request that our recommendation be accompanied by just such examples as might be used in teaching what it means, examples drawn from a variety of disciplines in which research on human subjects is conducted—just such examples as we have supplied. Any research that would impose no more risk of harm on its subjects than those would impose is also minimal risk research.

And we are recommending that if a research project would impose no more than minimal risk of harm on its subjects, then it *therefore* should be exempt from the requirement of IRB approval.

We use "exempt" in its commonsense meaning, as we put it in our 2006 report and repeat now: "straightforwardly exempt, with no requirement of IRB approval of the exemption." Then who or what is to decide that the project is exempt? We say the researcher. We believe now, as we believed in 2006, that researchers should be allowed to determine themselves whether their projects are exempt from regulation.

In the years after 1981, when the regulations first included a list of exemptions, the IRB system provoked relatively few complaints of infringement of academic freedom. Then, in 1995, the Department of Health and Human Services recommended that "investigators should not have the authority to make an independent determination that research involving human subjects is exempt," effectively turning "exempt" research into nonexempt research. Why? The 1995 recommendation was not supported by an official finding of fact—as it might have been, a report showing that researchers were making poor assessments of risk. Rather, the recommendation appears to have been a response to a general moral anger initially provoked by the appearance of newspaper reports in 1993 disclosing government-sponsored experiments on the effects of radiation on human subjects that had been carried out during and shortly after World War II.[12] Not surprisingly, the complaints of infringement of academic freedom swelled into a chorus after 1995. The rules had fundamentally changed: the mistrust of researchers that is expressed in the 1995 recommendation, and enforced since then, is quite remarkable.

There is, of course, a difference between the exemptions we recommended in 2006 and the exemptions we recommend now. Deciding whether the methodology of a project "consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places" (the exemptions we recommended in 2006) is presumably simple enough, as is deciding whether the methodology of a project meets condition (b) of our current recommendation. But deciding whether a project meets condition (a) of our current recommendation is another matter. It is obvious that there is more room for differences of opinion in the case of decisions about whether a project would impose no more than a minimal risk of harm on its subjects.

However, it should be recognized that differences of opinion about whether a project's methodology is a minimal risk methodology are not at all likely to be about clear cases of the kinds we have listed above; they are very likely to be about borderline cases.[13] The borderline cases may be what could be called ontologically borderline cases, that is, cases in which there just is no answer to the question whether the methodology is a minimal risk methodology. (How low must a risk be to be a very low risk?) Or they may be what could be called epistemologically borderline cases, that is, cases in which there is no evidence available at the

and a research project qualifies for it if the research imposes no more than minimal risk of harm on its subjects. Our recommendation calls for a project to be straightforwardly exempt if it meets that condition.

12. See Schrag, *Ethical Imperialism*, 130–36.

13. Kim, Ubel, and De Vries point this out in "Pruning the Regulatory Tree."

time that would settle whether the methodology is a minimal risk methodology. (It may be precisely from learning about what produced past mistakes about risk that researchers learn whether a given methodology is a minimal risk methodology.) Either way, IRBs are a fortiori no better placed to decide whether the methodology is a minimal risk methodology than researchers themselves are.

Moreover, we have no objection to an institution's (or a department's) choosing a person to serve as adviser on research risks; and it is an attractive idea that the institution (or department) recommend that novice researchers, and any experienced researchers who are in doubt, consult with that person at the outset. (Students who conduct research are already under advisement by their teachers or supervisors.)

In addition, departments typically, and all surely should, keep a record of the research done by their members, of the impact the research had on its subjects, and of the scientific conclusions it arrived at.

It is of course possible that a given researcher would take advantage of the privilege of deciding whether his or her methodology is a minimal risk methodology, deliberately proceeding while knowing that it is not. But we see no more reason for believing that researchers would do this than that they would deliberately carry out IRB-approved research improperly or that they would deliberately break any other important safety-protecting institutional rule. There is no reason at all for believing that researchers who abide by moral rules in their choice of research projects and in conducting the research do so only because their IRBs impose those requirements on them. And a researcher who is thought to have deliberately proceeded while knowing that the methodology of his or her project is not a minimal risk methodology can be charged in accordance with the institution's procedures for hearing charges of institutional misconduct, as can a researcher who does not know that his or her project would impose a more than minimal risk of harm on its subjects but ought to have known.

Finally, although researchers may make mistakes in deciding whether their research methodology would be a minimal risk methodology, we think that the alternative—namely, requiring that *all* research projects be approved by an IRB or an IRB surrogate—is markedly worse in its impact on both academic freedom and scientific research.

We were pleased to find that the ANPRM itself expresses doubt about the impact of the 1995 recommendation: it says that the constraint the recommendation imposes "appears to slow research without adding significant protection to subjects" (76 FR 44520). We can think of no one single emendation in the current regulations that would contribute more to the improvement of the IRB system than a rescinding of that recommendation.

3. As we said in the preceding section, it is a quite general feature of the current regulations that they have the following structure: they list types of research that are exempt from IRB assessment, all others requiring it.

There was one organization in our sample of responses to the ANPRM that recommended what looks like a change in regulation structure, namely, the American Anthropological Association (AAA). Its response recommends that "a revised Common Rule apply only to the following two kinds of work":

1. Biomedical and other *study procedures involving risks of physical harm to human participants*: that is, more specifically, harm defined in 76 FR 44515 II(A) as "characterized by short term or long term damage to the body such as pain, bruising, infection, worsening current disease states, long term symptoms, or even death."
2. Human experimentation and other *methodologies whose results depend for their validity on limiting or controlling the information available to research subjects*: that is, study designs reliant either on the passive withholding of information concerning what the study is about or on the active provision of misinformation: e.g., the use of placebos in biomedical clinical trials; the use of confederates in behavioral research concerning competition, conformity, and the like; and the deceptive presentation of fictional narratives as actual news reports in social research concerning public opinion.[14]

14. We quote here from the AAA's formal, highlighted statement of its recommendation and thus take it to say only the following: research on human subjects should be required to have IRB approval *only if* its methodology meets either the condition in clause 1 or the condition in clause 2.

However, a later passage in the response suggests that its authors may have meant something markedly stronger, namely, that research on human subjects should be required to have IRB approval *if and only if* its methodology meets either the condition in clause 1 or the condition in clause 2.

This strong, firm recommendation is of considerable interest.

We think that its clause 1 is too strong, however, and also, if interpreted literally, not strong enough. We first describe the way in which it is not strong enough. Every research methodology imposes some risk of physical harm. (As we said above, it is possible that if researchers ask a randomly chosen subject about his voting preferences, they will thereby cause him to drop dead.) Thus interpreted literally, every research methodology trivially meets clause 1. But we are sure that the AAA meant to say something stronger than that: we are sure it meant to single out research projects that impose (not just *a* risk of physical harm but) a more than minimal risk of physical harm.

The way in which clause 1 is too strong is as follows. Causing a person to undergo a bruise, an infection, a worsening of the person's current disease state, or death is on any view causing the person a harm—a physical harm, as the AAA summarizes these harms. What of causing a person to undergo psychotic episodes, such as hallucinations, or longer or shorter episodes of mental impairment or incapacitation, such as incoherence or memory loss? (Many people who were subjects in LSD tests were thereby caused to undergo such episodes.) What of causing a person to acquire a mental illness? These are all instances of causing a person a harm. How shall we summarize them? It seems suitable to call them psychological harms. Then it is not plausible to think that a project's imposing a more than minimal risk of physical harm in particular is necessary for requiring IRB approval of it; its imposing a more than minimal risk of either physical *or* psychological harm is more plausibly thought to be what is necessary.

Under the current regulations, a research project's imposing a more than minimal risk of harm—either physical or psychological harm—is sufficient for requiring IRB approval of it. However, the inclusion of psychological harm has provoked vehement objection over the years. One of the organizations in our sample—the American Educational Research Association—reports that this requirement has resulted in "unneeded reviews and unnecessary regulation of important but low risk [social and behavioral science] research," since IRBs have been encouraged to regard such "negative" psychological episodes as "boredom, worry, frustration, annoyance, stress, upset, guilt, and loss of self-confidence" as psychological harms. As we mentioned earlier, horror stories in the literature on IRBs have included instances in which IRBs refuse to approve of research surveys on the ground that their subjects might be dismayed or embarrassed by the questions put to them. The AAA report concludes from this history that the concept "psychological risk" "is a slippery, inherently subjective concept and should be dropped."

This is unquestionably a serious problem. The question is what to do about it, for research that would impose a more than minimal risk of psychotic episodes, mental impairment, or mental illness is as plausibly viewable as requiring IRB approval as research that would impose a more than minimal risk of physical harm.

One option is simply to emend the AAA's recommendation, adding a list of psychological harms—thus replacing "physical harm" by "physical harm or psychotic episodes, mental impairment, or mental illness." Another is to supply the general principle in virtue of which psychotic episodes, mental impairment, or mental illness belong on the list. That principle, it is plausible to think, is that they are psychological *harms*. They are not merely negative psychological episodes like boredom and embarrassment. Central to the concept "harm" are the concepts "damage" and "injury." If Smith's speech bores his hearers, then other things being equal, he does not thereby *damage* them; if Jones conducts a survey and embarrasses some of those she puts questions to, then other things being equal, she does not thereby *injure* them. Other things being equal, those whom Smith bores and Jones embarrasses remain hale and healthy throughout those episodes of boredom and embarrassment.

The borderline between negative psychological episodes and psychological harms is plainly thick, thicker perhaps than the borderline between minimal

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The passage we refer to says about their recommendation that it "stipulates that all research that requires the withholding of information as a basic condition for its validity (together with all research that depends upon systematic and active deception as a methodological tool) should be subject to some form of active IRB review." Thus, their recommendation stipulates that *if* a research project meets the condition in clause 2, then it should be required to have IRB approval. Perhaps they think that their recommendation also stipulates that *if* a research project meets the condition in clause 1, then it too should be required to have IRB approval. Let us suppose they do. (For why distinguish between the clauses in this respect?) Conjoin these two "if-recommendations" with their formal, highlighted "only-if-recommendation" and the result is the stronger claim that research on human subjects should be required to have IRB approval *if and only if* its methodology meets either the condition in clause 1 or the condition in clause 2.

We postpone discussion of this stronger claim.

risk and more than minimal risk. Thus differences of opinion about whether a psychological episode is or is not a harm may be more common than differences about whether a risk is or is not more minimal. That seems to us no reason for giving up the idea that there is an important difference between a negative psychological episode and a psychological harm, but rather a reason for giving examples of psychological harms just as we gave examples of no more than minimal risk methodologies—examples such as we gave just above, namely, psychotic episodes, mental impairment, and mental illness.[15]

We think, however, that the list of relevant harms should stop there. A research methodology might cause harms of other kinds. For example, as we said in the preceding section, a journalist might impose a considerably more than minimal risk of harm on a person by the question he or she asks in the course of a public interview. So also for researchers who ask such questions in public. We drew attention to the possibility of replying that the journalist or the researchers do not cause the harm that ensues, if harm ensues; rather, the people interviewed caused themselves the harm. Let us ask a different question here, namely, what kind of harm is the harm that gets caused in such cases? Interviewing in public imposes no more than a minimal risk of either physical or psychological harm; the harm of which it might impose a more than minimal risk is what is sometimes called social harm—damage or injury to reputation or employability.

Nevertheless, we recommend that social harms be excluded from consideration by IRBs.

In our 2006 report, we complained that we can see no "even relatively bright line" between cases in which a researcher might damage a subject's reputation and cases in which he or she would not, "given the immense variety of considerations on which a person's reputation rests in one or another community" of which he or she is a member. That is a complaint that the borderline between cases in which the researcher would damage a subject's reputation and cases in which he or she would not is particularly thick. That is surely right. But something else is also at stake here, and we think it matters more.

Under the current regulations, IRBs are encouraged to take all but one kind of harm into consideration. The exception is described as follows: "The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility" (45 CFR 46.111[a][2]).Why make an exception for that kind of harm? The regulations do not say. A plausible hypothesis is that encouraging IRBs to assess whether the long-range effects of a research project are likely to include harms and, if so, how grave those harms would be is encouraging them to bring to bear their own beliefs about what people at large—people other than just the research subjects—are likely to feel, think, and do in consequence of the research, and about how good or bad those outcomes would be.[16] The future is a big country, however, and an IRB member's beliefs about what people will feel, think, and do there, and how good or bad those outcomes will be, may be entirely idiosyncratic. There is no way in which it can be ensured that IRBs so encouraged would make assessments of the research projects brought to them that would be appropriately respectful of the academic freedom of the researchers and the possible scientific value of their projects.

For IRBs to take possible social harms to the subjects into consideration is not for them to spread nearly as broadly as that, but it is for them to spread inappropriately broadly. For things done and said now can have an impact on what others will feel, think, and do to and about a research subject long into the future, and there is no way in which IRBs can responsibly make assessments of how they will in advance—responsibly enough to do justice to the researcher and his or her project.

If social harms are excluded from consideration by IRBs, then the recommendation we arrived at in examining exemptions in the preceding section really could have done without its second disjunct ("research on autonomous adults should be exempt from IRB approval if its methodology . . . consists entirely in speech or writing, freely engaged in, between subject

15. What about pain? The AAA gave pain as an example of a physical harm. Pain is presumably always caused by some physical harm, but it is arguable that it is not itself a physical harm. Compare hallucinations, which are always caused by physical harms but are not themselves physical harms. We see no need to answer the question whether pain is a physical or psychological harm; it is enough for present purposes that, either way, causing pain is injuring and thus is causing a harm.

16. Adoption of the exception by federal policy makers seems to have been provoked by a desire to avoid repetition of a controversy that broke out at the University of California, Berkeley, in the early 1970s, about whether a university may acceptably permit constraints on research that are justified by beliefs about the future of the kind we mention. See Schrag, *Ethical Imperialism*, 45–46, 70–71.

and researcher"). For where a research project's methodology would consist entirely in speech or writing, freely engaged in, between subject and researcher, then it imposes no more than a minimal risk of physical or mental harm on its subjects, and hence is exempt under the first disjunct ("research on autonomous adults should be exempt . . . if its methodology . . . imposes no more than minimal risk of harm on its subjects"). However, we see no need to revise the recommendation of the preceding section since, as we said, what is peculiarly objectionable in requiring IRB approval of interviews and the like is that it interferes with freedom of speech.

In sum, then, we recommend revising the AAA's recommendation so that its clause 1 applies only to research methodologies that impose a more than minimal risk of physical or psychological harm, those being the only kinds of harm an IRB is licensed to attend to.

Let us now look at the second clause of the AAA's recommendation. It applies to methodologies whose results "depend for their validity" on controlling the information available to the subjects, or deliberately deceiving them.

We think that the fact that a research project's results would depend for their validity in either of those two ways is irrelevant to whether it should be required to have IRB approval.

Consider the AAA's first example of a methodology in which the information available to the subjects is controlled: "the use of placebos in biomedical clinical trials." Most (we suspect all) use of placebos in contemporary biomedical clinical trials does not involve deception: prospective subjects are told what the study will be about, that some subjects will receive the medication being tested and others will not, and that the subjects will not know which group they fall into. Thus the researchers do not misinform the prospective subjects. And while those who consent to becoming subjects will be ignorant of which group they fall into, they will not have been deceived about anything. We think it likely that most biomedical clinical trials impose a more than minimal risk of harm on their subjects and for that reason may well be thought to require IRB approval. Whether or not they do, we think that the fact that they rely on the use of placebos in the way we described does not by itself warrant requiring IRB approval of them.

Deception is another matter. It will have been noticed that the recommendation we described in the preceding section—like our recommendation in 2006 and like the current federal regulations—does not say or imply that a researcher's need to deceive his or her subjects should mark the research as requiring IRB review. Still, it is certainly plausible (it really needs no saying) that, other things being equal, one ought not deceive others, and it might well be asked why we do not think that a project's requiring deceit is sufficient, by itself, to mark it as requiring IRB approval.

Our reason lies in the familiar fact that other things are not always equal. That is, the prohibition against deceit is not absolute: deceiving is justified if engaging in it would have a sufficiently valuable outcome. If that were not the case, then turning the research over to an IRB would be pointless, for there would not be anything about the research that an IRB could acceptably regard as warranting its being carried out.

Suppose, then, that a researcher needs to deceive those who have consented to be subjects of his or her research if the research is to be properly carried out—or to deceive prospective subjects about the nature of the research in order to get them to consent to being subjects. And suppose that the research would not impose a more than minimal risk of harm on its subjects. It is entirely reasonable to believe that if the value of the information to be obtained by the research is sufficiently great, the use of the deceit is justified. It is, after all, only by virtue of arriving at that very conclusion about the research that an IRB could itself approve of it. However, as we said in our 2006 report about the idea of turning over to an IRB the question whether that conclusion is warranted, "there could hardly be a more obvious potential threat to academic freedom." We have no objection to a department's having mechanisms by means of which its members who are novice researchers can be advised about the importance of the information that their proposed research would yield; in any case, students already have such advisers in the persons of the faculty members who supervise their work. But we see no reason to think IRBs are more capable of assessing the importance of a research project than researchers are, just as we see no reason to think IRBs more capable of assessing whether research projects would impose a more than minimal risk of harm.

In sum, we think that the AAA's recommendation would be improved if it were strengthened by omitting its clause 2 altogether, thus altering it to say that research on human subjects ("human participants") should be required to have IRB approval *only if* its methodology imposes more than a minimal risk of physical or psychological harm on its subjects.

We think that one final revision is called for, however, for it is arguable that the AAA's recommendation is overly strong in a way that we have not so far mentioned. We have in mind the fact that the human subjects ("human participants") on whom research is done differ widely. Some are, as we have been putting it, "autonomous adults." Others are, as the federal regulations put it, "vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons." We think it very plausible that IRB approval should be required for research on autonomous adults only if it would impose more than a minimal risk of physical or psychological harm on them. But we think it plausibly arguable that IRB approval should be required for research on at least *some* members of vulnerable populations even if it would not impose more than a minimal risk of physical or psychological harm on them.

Which members? There is no general answer to that quite general question. The further conditions the members of a vulnerable population must meet if it is to be plausibly arguable that IRB approval of research on them is required is presumably a function of what marks the members of the population as vulnerable. But what marks pregnant women as vulnerable is obviously not the same as what marks the mentally disabled as vulnerable. What marks prisoners as vulnerable is not the same as what marks children as vulnerable. Indeed "children" itself refers to a class whose members include infants and seventeen-year-olds, and they are vulnerable for very different reasons. The class of economically or educationally disadvantaged persons is at least as large and varied.

Producing plausible necessary conditions for requiring IRB approval of research on members of vulnerable populations is a complex problem, and we do not try to solve it here. (Nor did the AAA try to solve it in drawing up its report.) Whatever is to be said about this issue, however, we think that the following modification of the AAA's recommendation is very attractive:

> Research on autonomous adults should be required to have IRB approval only if its methodology imposes more than a minimal risk of physical or psychological harm on its subjects.

For brevity in the statement of the recommendation, we do not include examples of physical or psychological harms in it. However, accompanying the recommendation with such a list—as also with a list of examples of minimal risk of harm (as in the preceding section)—is certainly called for.

4. It would be no wonder if the "requirement recommendation" we arrived at in the preceding section looked familiar. Here is the "exemption recommendation" we had made in section 2, above:

> Research on autonomous adults should be exempt from IRB approval (straightforwardly exempt, with no provisos and no requirement of IRB approval of the exemption) *if* its methodology either
>
> (a) imposes no more than minimal risk of harm on its subjects, or
>
> (b) consists entirely in speech or writing, freely engaged in, between subject and researcher.

The requirement recommendation should look familiar since, as we know, clause (b) in the exemption recommendation is superfluous: it can be omitted, since every methodology that meets condition (b) also meets condition (a), given that social harm is excluded from consideration by IRBs; thus the exemption recommendation says that a project should be exempt from IRB approval if it imposes no more than a minimal risk of physical or psychological harm. And the requirement recommendation says that a project should be required to have IRB approval only if it imposes more than a minimal risk of physical or psychological harm.

Indeed, though we thought that in turning to the AAA's response we would be looking at a recommendation with a different regulation structure, we are not, for the two recommendations are equivalent. While the exemption recommendation supplies sufficient conditions for exempting a project from IRB approval, the requirement recommendation does not supply sufficient conditions for requiring IRB approval. In supplying only necessary conditions for requiring IRB approval, the requirement recommendation in fact supplies only sufficient conditions—as it turns out, the same sufficient conditions—for exempting from IRB approval.

The requirement recommendation can be strengthened. Consider the following strengthened requirement recommendation:

> Research on autonomous adults should be required to have IRB approval *if and only if* its

methodology imposes more than a minimal risk of physical or psychological harm on its subjects.[17]

That it is stronger than the unstrengthened requirement and exemption recommendations emerges if we notice that it entails that some research projects should be required to have IRB approval, whereas the unstrengthened requirement and exemption recommendations are consistent with its being the case that no research at all should be required to have IRB approval. The unstrengthened requirement and exemption recommendations can be understood to say, in effect, that if we must have IRBs regulating research on human subjects (which leaves it open that we should not), then at any rate, all projects that would impose no more than a minimal risk should be exempt. Alternatively put, only projects that would impose more than minimal risk should be required to have IRB approval.

On some views, that is as it should be. On those views, the unstrengthened requirement and exemption recommendations should be adopted, for adopting them really would improve the IRB system, but the IRB system is radically defective: it needs more than emending; it needs replacing. Whether those views are right, it pays to distinguish the question what emendations would improve the current system from the deeper question whether the current system should be replaced. We therefore postpone discussion of the deeper question. Meanwhile, three more issues call for attention.

5. The first is concern (e) on our list of concerns expressed by respondents in our sample of responses to the ANPRM, namely, concern about the regulations governing storage and retention of research data. As we said, all of the responses to the ANPRM that mentioned these regulations expressed dissatisfaction with them. We have to bypass many of the issues they raise; we discuss one in particular.

In our 2006 report, we recommended that the risks of harm that IRBs focus on be restricted to the risks of harm imposed by the research methodologies of the projects they assess. We continue to believe that they should be so restricted. We said that we can see no reason for believing that IRB members are any better equipped to assess practices for protecting research data in a discipline than members of the relevant discipline are.

But while we continue to think that the disciplines' recommendations about data protection are to be respected, the difficulties have been increasing in recent years. Data stored on computers are increasingly threatened by sophisticated methods of interpretation and invasion, and it is increasingly difficult to protect research data against legal démarche.

On the other hand, these difficulties are no novelty at the institutions under whose auspices research on human subjects is conducted, since the institutions have other long-standing needs for data protection. Hospitals must protect data about their patients; colleges and universities must keep a wide range of student data confidential; employers who provide, support, or contribute to medical care for their employees must protect the files in which information about their health is stored. Access to advice from experts on computer security and from lawyers is already available, or routes to obtain it are already open.

We suggest that the data collected in conducting research at an institution should be regarded, similarly, as a matter of concern to the institution. The institution should encourage the researchers attached to it to seek advice from the appropriate office or officer about how to protect their research data. We have no objection to the institution's going further and requiring its researchers to obtain approval of their data-protection plans in advance of conducting the kind of research in which a breach of confidentiality of its results would cause harm to its subjects.

What is crucial, in our view, is that as we said in 2006, there is no reason for believing that IRB members are especially competent to assess practices for protecting research data. Doing that requires experts, whom the institution can call on for help.

6. Item (f) in our list of concerns expressed by respondents in our sample of responses to the ANPRM is that most institutions do not provide an appeal process for a researcher whose project is (as the researcher thinks) gutted by his or her IRB or outright rejected by it. All of those responses that mentioned lack of an appeal process strongly objected to the lack. We wholly agree, for two reasons. The first is the fact that IRB approval is necessary for obtaining federal support for the researcher's project. Given that other funding is scarce, an IRB rejection of a project may well kill it. Second, and even more important, most institutions require IRB approval for all nonexempt research done under their auspices, and therefore an

17. In note 14, we drew attention to the fact that the AAA may have meant this markedly stronger thesis all along.

IRB rejection of a project at one of those institutions certainly does kill it.

So we think an appeal process should be made available. The harder question is, What kind of appeal process? The current regulations permit institutions to have an appeal process and do not require that the appellate body be an IRB. But they do require IRB approval for the research to be carried out. Thus, if the institution's appellate body is not itself an IRB, then if it agrees with the appellant, it can at most send the appellant back to the IRB that rejected his or her project or to another IRB at the same institution.[18] It would be no surprise if that seemed unsatisfactory to many. But what alternative is possible?

We are inclined to think that the problem here is markedly less difficult than has been thought—for colleges and universities at any rate. (We will from here on say "universities" for short.)

Suppose a university faculty member submits his or her research project to the campus IRB, and the IRB rejects it, and the university's administration therefore forbids the faculty member from conducting the research there. And suppose the faculty member thinks that the IRB's decision was wrong and therefore that the administration acted wrongly in forbidding the faculty member from conducting the research there. A faculty member's duties include research as well as teaching, so the gravamen of his or her charge against the administration is: violation of academic freedom. We therefore think it clear that the faculty member's charge against the administration should be brought to the body on campus whose role is precisely to hear charges of violation of academic freedom, namely, the institution's faculty grievance committee. We see no reason at all for believing that while that committee is competent to assess the propriety of the administration's action where the action rests on decisions made anywhere on campus, it is incompetent to assess the propriety of the administration's action where the action rests on the decision of an IRB in particular. (With the exception of its member who is unaffiliated, most, if not all, of the members of a university's IRB are faculty members, just as most, if not all, of the members of the faculty's grievance committee are, and there is no reason for believing that they have the relevant expertise while serving on one committee but not while serving on the other.) It is not open to an institution that respects the academic freedom of its faculty to refuse to allow a faculty member's charge of violation of academic freedom to be heard by the faculty's grievance committee.

It would of course be open to the committee to hear evidence presented by the IRB just as it would be open to it to hear evidence presented by any other person or group or organization on campus.

Moreover, it would be open to the committee to conclude that the complainant's appeal was unwarranted. Or, alternatively, to conclude that the case was unclear, and that the project should be resubmitted to the IRB that rejected it with instructions to reconsider it in light of the grievance committee's grounds for believing that the IRB's decision may have been a violation of the complainant's academic freedom. Or to conclude that the case should be submitted to a different IRB.

Or to conclude that the complainant's appeal was entirely warranted, that the decision of the IRB was unjustified, and that the administration's action was straightforwardly a violation of the complainant's academic freedom, and therefore that the faculty member may conduct his or her research. Such cases would be at most very rare on a campus with an experienced IRB, one that is not tempted by its role to indulge in paternalism and is respectful of both the value of scientific research and the academic freedom of the faculty that conducts it. However, good governance in a university requires that this be an open possibility.

7. Finally, item (g) on the list of concerns expressed by respondents in our sample issues from the fact that while the current regulations allow institutions to adopt different review procedures for research on human subjects that is not federally funded, most institutions do not. The ANPRM now requests comment on the proposal that HHS should close that option. As we said, some of the responses in our sample support this proposal, but others strongly oppose it.

In our 2006 report, we recommended that 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." Very

18. Here is the remarkably complex membership of the appeals committee at Virginia Commonwealth University: "The Director of the Office for Research Compliance and Education serves as Chair, and the following are the other voting members: Chairs/Vice Chairs of other IRBs than the one that rejected the appellant's project, a nonaffiliated member from an IRB not involved with producing the decision being appealed, a patient advocate, the Director of the Office of Research Subjects Protection, and a member selected by the researcher, a member who is, if possible, a current or past member of an IRB." If the appeals committee disagrees with the decision of the IRB being appealed, the protocol is sent to a different IRB for full review.

few universities have done so, and, in the case of those few that have, the innovations they adopted have been minor. For example, at one institution, continuing IRB review of ongoing non-federally funded research takes place every three years rather than every year.[19] Nevertheless, we agree with the American Educational Research Association—an organization in our sample—which responded that "giving institutions some leeway to experiment with subject protection mechanisms that differ from those in the Common Rule may reduce costs, increase subject protection, and perhaps suggest new mechanisms that might be incorporated into the Common Rule." We therefore continue to recommend that universities take advantage of the option while it is available, and we oppose the ANPRM's proposal that the option be closed.

* * *

We said at the outset that, judging from the ANPRM, HHS intends to give the current regulations a deep reconsideration at this time.

As things now stand, the IRB system assembles local committees whose members have no special competence in assessing research projects in the wide range of disciplines they are called on to assess, whose approval is required for an only minimally restricted range of research projects and who are invited to bring to bear in assessing them an only minimally restricted body of what they take to be information, who are only minimally restricted in the demands they may make on the researchers, and whose judgments about whether to permit the research to be carried out at all are, in most institutions, final. When one steps back from it, one can find oneself amazed that such an institution has developed on university campuses across the country.

We have recommended some revisions in the current regulations that we believe would considerably curtail the IRBs' power and thereby reduce the system's objectionable features. But by how much? It is striking that nobody is now in a position to say, because nobody has structured, reliable empirical evidence of how well the system is working, much less of how well or ill it would be affected by this or that emendation.

We have been drawing attention to complaints about the system. We should also draw attention to the fact that many people report favorable experiences with it. Many researchers have thanked IRBs for helping them think through the moral issues raised by their work, and many present and former IRB members report that their IRB contributed substantially to developing the research projects they assessed and to protecting the research subjects. However, there has been no comprehensive formal study of whether the benefits the system yields are on balance worth the costs it imposes.

Moreover, government agents have themselves contributed to a lack of clarity on this matter. The December 2011 report of the Presidential Commission for the Study of Bioethical Issues declared: "The current U.S. system provides substantial protections for the health, rights, and welfare of research subjects and, in general, serves to 'protect people from harm or unethical treatment' when they volunteer to participate as subjects in scientific studies supported by the federal government." Yet the report also declared that "there remains a dearth of knowledge about the actual efficacy of human subjects protections" and recommended that "the federal government support an expanded operational research agenda to study the effectiveness of human subjects protections."[20] Thus having declared that the IRB system has been largely successful, the commission went on to call for research to find out whether it has been successful.

Why has there not already been a comprehensive study of the IRB system—especially given that social scientists who might have been expected to conduct it have been at least as hampered by the system as the members of any other disciplines? Part of the trouble may be that it is not at all clear how such a study should be designed if it is to warrant conclusions about how well the system is working on balance. (How, for example, is one to assess whether important research has been stifled by the IRB system and, if so,

19. The Flexibility Coalition is an organization whose aim is to encourage sharing ideas about how to find flexibility within the current regulations and, in particular, to encourage innovation in ways of reviewing non-federally funded research. For information, see http://www.usc.edu/admin/oprs/flex.

20. Both passages are from the commission's report, *Moral Science*, the first from page 42, the second from page 55. The commission's members include a senior official at HHS, Dr. Christine Grady, Chief of the Department of Bioethics of the Clinical Center of the National Institutes of Health, who wrote in a recent article: "It is unclear to what extent IRBs achieve their goal of enhancing participant protection and whether they unnecessarily impede or create barriers to valuable and ethically appropriate clinical research" ("Do IRBs Protect Human Research Participants?" *Journal of the American Medical Association* 304 [2010]: 1122–23). (For some references to claims that IRBs create barriers to important social science research, see note 21.)

by how much?[21]) Moreover, it might well be expected to be very expensive. A press release issued by HHS on January 12, 2012, is therefore encouraging: "The National Institutes of Health is committing $1 million to support research that will be used to evaluate the impact of the revisions to the HHS regulations governing human subject research that are currently being considered. Assessing the impact of the revisions that are ultimately implemented will be critical to the development of an evidence-based approach to ensuring the effectiveness of human research subject protections."[22] We suspect that the $1 million will be run through fairly quickly in conducting the required study, but we think this an excellent (if long overdue) commitment: the development of an "evidence-based" approach to regulating research on human subjects would be very welcome indeed.

It is to be hoped that the research to be carried out would also contribute to making an evidence-based decision on the deeper question whether the IRB system needs more than emending and instead needs to be replaced. We say "replaced" rather than simply eliminated, for we think it out of the question that the clock be turned back to a time when there was no regulation at all of research on human subjects. (In any case, it would be politically impossible to turn it back.) But a number of alternative systems have been proposed (we mention two in a footnote), and it would be very helpful to obtain some empirical ground for concluding that the more intuitively attractive of the alternatives would function more or less well than the IRB system does.[23] Armchair speculation on the part of an experienced researcher who is in possession of information about the experiences of others, as well as about his or her own experiences, is a very good reason for predictions. But such speculation is compatible with bias of various kinds, and regulations as important to the community as those governing research on human subjects should be supported by evidence with a broader base.

Meanwhile, however, there is room for improvement in the information that is made available to IRBs and researchers. The Office for Human Research Protections, in concert with the relevant learned societies, should publish guidelines and case studies for researchers to consult when preparing their projects and for IRBs to consult when reviewing them. Institutions could helpfully publish yearly lists of research projects begun under their auspices, whether or not they required IRB approval.

We add that there is room for improvement in the information that the government itself relies on for policy development. In its response to the ANPRM, the AAA proposed that a commission be constituted of social scientists (such as sociologists and anthropologists) and members of disciplines in the humanities that conduct research on human subjects (such as historians and legal scholars). The development of government regulation of research on human subjects has chiefly relied on information obtained from the medical research community, whose concerns differ in crucial ways from those of the social and cultural research community; the constitution of such a commission as the AAA proposes would enable the government to obtain guidance in developing policy appropriate to research in those fields. We endorse this proposal.

Finally, the fact that more than eleven hundred responses were submitted to the government's ANPRM suggests there is a deep and widespread dissatisfaction with the current regulations. We express a hope that comparably deep rethinking of the current regulations will be undertaken in response to them. ■

21. Many commentators have claimed that important social science research has been foregone because of the high barriers placed on it by IRBs. See, for example, Schrag, *Ethical Imperialism*, 169–70; Caroline H. Bledsoe, Bruce Sherin, Adam G. Galinsky, Nathalia M. Headley, Carol A. Heimer, Erik Kjeldgaard, James T. Lindgren, Jon D. Miller, Michael E. Roloff, and David H. Uttal, "Regulating Creativity: Research and Survival in the IRB Iron Cage," *Northwestern University Law Review* 101 (2007): 618–21; Will C. van den Hoonaard and Anita Connolly, "Anthropological Research in Light of Research-Ethics Review: Canadian Master's Theses, 1995–2004," *Journal of Empirical Research on Human Research Ethics* 1 (June 2006): 59–69; Mary Brydon-Miller and Davydd Greenwood, "A Re-examination of the Relationship between Action Research and Human Subjects Review Processes," *Action Research* 4 (2006): 123; and "The Impact of Institutional Review Boards (IRBs) on Law and Society Researchers," report of the Membership and Professional Issues Committee of the Law and Society Association, July 24, 2007. "Communication Scholars' Narratives of IRB Experiences," *Journal of Applied Communication Research* 33 (August 2005): 204–30, consists of a set of reports by researchers on their experiences with their local IRBs, many of whom describe foregone research projects.

22. The press release in its entirety can be found at http://www.hhs.gov/news/press/2012pres/01/20120110a.html.

23. A recent essay in *Science* recommends a system of audits and retrospective review: Robert Klitzman and Paul S. Appelbaum, "To Protect Human Subjects, Review What Was Done, Not Proposed," *Science* 335, no. 6076 (March 30, 2012): 1576–77. Another essay recommends a more centralized review: Rita McWilliams, Carl W. Hebden, and Adele M. K. Gilpin, "Concept Paper: A Virtual Centralized IRB System," *Accountability in Research* 13, no. 1 (2006): 25–45.

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

CATHERINE ELGIN (Philosophy)
Harvard University

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

ZACHARY SCHRAG (History)
George Mason University

JONATHAN KNIGHT (Political Science)
Warwick, Rhode Island, *consultant*

B. ROBERT KREISER, *staff*

The Subcommittee