

Dr. Jerry Menikoff
Director, Office for Human Research Protections
US Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852

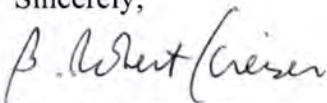
Dear Dr. Menikoff:

I am writing on behalf of the American Association of University Professors (AAUP) for the purpose of submitting the attached comments on the 26 July 2011 advance notice of proposed rulemaking, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators."

The AAUP is an organization of approximately 45,000 faculty members and research scholars in all academic disciplines, and is dedicated to advancing the interests of higher education. Founded in 1915, the Association is committed to the defense of academic freedom and the free exchange of ideas in scholarly work. One of the AAUP's principal tasks is the formulation of national standards, often in conjunction with other higher education organizations, for the protection of academic freedom and other important aspects of university life. These standards serve to define fundamental professional values and standards for higher education, and to ensure higher education's contribution to the common good.

Since 1981, the AAUP has expressed concern about the potential for human subjects research protections to interfere with academic freedom, most recently in our 2006 report, "Academic Freedom and the Institutional Review Board." We are grateful to the authors of the ANPRM for acknowledging that work and for this opportunity to comment on the proposed changes to federal regulations.

Sincerely,



B. Robert Kreiser
Senior Program Officer
Department of Academic Freedom, Tenure, and Governance

Enclosure

cc: Professor Cary Nelson, President, American Association of University Professors
Professor David M. Rabban, Chair, Committee A on Academic Freedom and Tenure
Professor Judith J. Thomson, Chair, Subcommittee on Academic Freedom and the
Institutional Review Board

Comments in Reply to “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators”

I. IRBs should evaluate risk based on empirical evidence

General comments on the assessment of risk

We agree with the premise of question 4 that IRBs frequently restrict research based on fantastical, rather than reasonable, risk. We concur with the 1999 recommendation of the Working Group of the Human Subjects Research Subcommittee of the National Science and Technology Council: “In determining whether there might be a reasonable risk or damage related to divulging the sensitive information, etc., it is not enough that there be merely some hypothetical possible risk that can be construed. Rather, the risks resulting from disclosure must be readily appreciable and significant.”¹

In 2006, we noted that “IRB members are instructed to form their own view of the risks their colleagues’ research would impose on its subjects.”² Any regulation should be accompanied by guidance recommending that IRBs base their decisions on empirical evidence. If a researcher can show that a given method is in regular use, and an IRB cannot show that the method regularly abuses research participants, the research should proceed.³ IRBs should also document the reasons for their decisions, something they seem to be doing now at a low rate.⁴

The University of Texas’s 2009 report, “Trust, Integrity, and Responsibility in the Conduct of Human Subjects Research,” encourages IRBs to act based on “evidence-based research” and “empirical studies.” The federal government should do the same.

Question 4: *Should the regulations be changed to indicate that IRBs should only consider “reasonably foreseeable risks or discomforts”?*

Answer. We support this change and suggest adding the word “significant” to describe the risks that may be considered.

Question 5: *What criteria can or should be used to determine with specificity whether a study’s psychological risks or other nonphysical, non-information risks, are greater than or less than minimal?*

¹ James D. Shelton, “How to Interpret the Federal Policy for the Protection of Human Subjects or ‘Common Rule’ (Part A),” *IRB: Ethics and Human Research* 21 (November-December 1999), 7.

² American Association of University Professors, “Research on Human Subjects: Academic Freedom and the Institutional Review Board,” 2006, <http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm>

³ Brian Mustanski, “Ethical and Regulatory Issues with Conducting Sexuality Research with LGBT Adolescents: A Call to Action for a Scientifically Informed Approach,” *Archives of Sexual Behavior*, published online 29 April 2011.

⁴ Survey Research Center, Institute for Social Research, University of Michigan, “2009 Follow-Up Survey of Investigator Experiences in Human Research,” December 2010, table 15.

Answer. IRBs and researchers should rely on existing empirical evidence and scholarship to determine whether a project presents risks greater than minimal. Projects using common methods should not be considered risky unless the IRB can show otherwise citing specific evidence.

***Question 6:** Are there survey instruments or specific types of questions that should be classified as greater than minimal risk? How should the characteristics of the study population (e.g., mental health patients) be taken into consideration in the risk assessment?*

Answer. We know that legally competent adults sometimes get upset when speaking with interviewers or completing surveys. However, we have not seen evidence that this problem merits restrictions on the ability of legally competent adults to speak with researchers. If a person's mental disability prevents that person from making informed choices, then oversight is appropriate.

II. We endorse the proposed “excused” category, provided that projects would truly be exempt “without any further qualifications”

General comments on the “excused” category

Under the current Common Rule, most social research is exempt from oversight unless “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.” But these are exceedingly vague terms.

As we observed in our 2006 report, the concern expressed in these provisos is with possible breaches of confidentiality, not with the possibility that the research might itself harm its subjects. Moreover, the vagueness of the regulations has been aggravated by federal guidance on exemptions. Since the mid-1990s, the federal recommendation that investigators not be permitted to make the exemption determination, combined with the threat of federal sanction for incorrect determinations, has led institutions to insist that only IRB members or staff can determine a project to be exempt. Thus, “exempt” no longer means exempt, leaving researchers unhappy and IRBs overwhelmed with work.

In our 1981 report, we found “considerable merit” in the proposal that “research using legally competent subjects that involves neither deceit nor intrusion upon the subject’s person nor denial or withholding of accustomed or necessary resources” be exempt from IRB oversight. We argued that “research of that kind should be exempt, even if it does impose a risk of harm on its subjects. Requiring IRB approval of such research is a positive invitation to the members of an IRB to act paternalistically.”⁵

Similarly, in 2006 we recommended “that research on autonomous adults [where the] methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—

⁵ American Association of University Professors, “Regulations Governing Research on Human Subjects,” *Academe*, December 1981.

straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.”⁶

We therefore applaud the proposal to “Clarify that routine review by an IRB staff member or some other person of such minimal risk exempt studies is neither required nor even recommended [and] Expand the current category 2 exemption (45 CFR 46.101(b)(2)) to include all studies involving educational tests, surveys, interviews, and similar procedures so long as the subjects are competent adults, without any further qualifications (but subject to the data security and information protection standards . . .).”

***Question 14:** Are these expansions in the types of studies that would qualify for this Excused category appropriate? Would these changes be likely to discourage individuals from participating in research? Might these changes result in inappropriately reduced protections for research subjects, or diminished attention to the principles of respect for persons, beneficence, and justice?*

Answer: In 1981 we noted that private persons are at liberty to conduct interviews, surveys, and observations without seeking IRB approval, and that legally competent subjects are capable of refusing to participate or withdrawing in the middle of an interview or survey. We do not believe that they need extra protection when the researcher receives federal funds or is associated with an institution that does.

***Question 15:** Beyond the expansions under consideration, are there other types of research studies that should qualify for the Excused category? Are there specific types of studies that are being considered for inclusion in these expansions that should not be included because they should undergo prospective review for ethical or other reasons before a researcher is allowed to commence the research?*

Answer: The current Common Rule exempts observation. If observation is to remain subject to the Common Rule, it should be excused. Since the exchange of documents is equivalent to an interview, this, too, should be excused. For example, a research participant might follow up an interview by sending an e-mail message or forwarding some old correspondence.

***Question 16:** Should research involving surveys and related methodologies qualify for the Excused category only if they do not involve topics that are emotionally charged, such as sexual or physical abuse? If so, what entity should be responsible for determining whether a topic is or is not emotionally charged?*

Answer. We do not think that “emotionally charged” questions should trigger a higher level of review. While what is an emotionally charged question will depend on several factors, including the nature of the research project and the phrasing of the question, experience has shown that IRBs tend to overestimate the risk of such questions. In these overestimations, IRBs can retard research and deprive both researchers and subjects of

⁶ American Association of University Professors, “Research on Human Subjects: Academic Freedom and the Institutional Review Board,” 2006, <http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm>.

conversations they find beneficial.⁷ Moreover, if asking an “emotionally charged” question triggers IRB review, institutions will inevitably start demanding that researchers submit questions for prior review. Thus, “excused” will not mean excused, just as “exempt” no longer means exempt.

Question 19: *Regarding the Excused category, should there be a brief waiting period (e.g., one week) before a researcher may commence research after submitting the one-page registration form, to allow institutions to look at the forms and determine if some studies should not be Excused?*

Answer. We oppose a waiting-period requirement, which could block important research. Some research must be planned and conducted quickly in response to breaking events; a waiting period could stifle such research.⁸ Conversely, we also note the need for a provision for evolving research. Anthropologist Alex Golub notes that in his work, “In some cases I interviewed people I’d known for years. I’d have breakfast or lunch with them and then schedule the official ‘interview’ for later on in the week.”⁹

Both problems might be solved by certifying researchers, rather than specific projects. That is, a researcher who completed training in one of the specified research methods and agreed to abide by the data protection rules would be allowed to conduct research using that method with any legally competent adult, with neither a waiting period nor fixed start and end dates.

Question 20: *The term “Excused” may not be the ideal term to describe the studies that will come within the proposed revision of the current category of exempt studies, given that these studies will be subject to some protections that are actually greater than those that currently exist. Might a term such as “Registered” better emphasize that these studies will in fact be subject to a variety of requirements designed to protect participants? We welcome other suggestions for alternative labels that might be more appropriate.*

Answer. Given the long history of IRB over-regulation, it is the excusal, not the requirements, that needs emphasis. We prefer “Excused.”

Question 21: *Is it appropriate to require institutions holding a Federalwide Assurance to conduct retrospective audits of a percentage of the Excused studies to make sure they qualify for inclusion in this category? Should the regulations specify a necessary minimum percentage of studies to be audited in order to satisfy the regulatory requirements? Should some other method besides a random selection be used to determine which Excused studies would be audited?*

⁷ Joan E. Sieber, “Protecting the Vulnerable: Who Are They?” *Journal of Empirical Research on Human Research Ethics* 3 (March 2008): 1-2.

⁸ Anthony J. Langlois, “Political Research and Human Research Ethics Committees,” *Australian Journal of Political Science* 46 (2011): 139-54.

⁹ Alex Golub, “Using informed consent forms in fieldwork,” *Savage Minds*, August 10th, 2007, <http://savageminds.org/2007/08/10/using-informed-consent-forms-in-fieldwork/>.

Answer. No one can predict the precise details needed to make a novel system like this work. Instead of beginning with any audit requirement, institutions should be encouraged to experiment with and develop audit mechanisms.

***Question 22:** Are retrospective audit mechanisms sufficient to provide adequate protections to subjects, as compared to having research undergo some type of review prior to a researcher receiving permission to begin a study? Might this new audit mechanism end up producing a greater burden than the current system? Do researchers possess the objectivity and expertise to make an initial assessment of whether their research qualifies for the Excused category? By allowing researchers to make their own determinations, without prospective independent review, will protections for some subjects be inappropriately weakened? If allowing researchers to make such determinations without independent review would generally be acceptable, are there nonetheless specific categories of studies included in the proposed expansion for which this change would inappropriately weaken protections for subjects? And will the use of a one-page registration form give institutions sufficient information to enable them to appropriately conduct the audits?*

Answer. As with question 21, no one can predict the precise details needed to make a novel system like this work. Instead of beginning with any audit requirement, the federal government should establish a system by which regulations and guidance can evolve in the light of experience and in response to concerns voiced by all those who are affected by the regulations.

***Question 28:** For research that requires IRB approval, the Common Rule does not currently require that the researcher always be allowed some form of appeal of a decision (e.g., disapproval of a project). Some institutions have voluntarily chosen to provide appeal mechanisms in some instances, by, for example, allowing the researcher to present the project to a different IRB, or by having it reviewed by a special “appeal” IRB that is composed of members chosen from among the membership of the institution’s other IRBs. Should the Common Rule include a requirement that every institution must provide an appropriate appeal mechanism? If so, what should be considered acceptable appeal mechanisms? Should such appeal mechanisms, or different ones, be available for appeals asserting that the investigation is not research, or that the research does not require IRB approval?*

Answer. In our 2000 staff report, “Institutional Review Boards and Social Science Research,” we found that “The researcher who suffers the sting of an adverse IRB decision is unlikely to be mollified by assurances that the board members did their best. What is needed is for some other body to consider a researcher’s complaint that the decision of the IRB was not full or fair.”¹⁰ Thus, an appeals process would not only protect researchers against arbitrary decisions by IRBs; it would also help IRBs by building credibility among researchers. The present requirement that only a fully constituted IRB can overturn the decision of another IRB imposes too great an administrative burden on institutions wishing to establish an appeal mechanism. One possibility would be to require institutions to offer an appeals process that could examine

¹⁰ <http://www.aaup.org/AAUP/comm/rep/A/protecting.htm>.

whether an IRB acted according to professional standards and remand the decision to the IRB, but that would not be empowered to approve research that an IRB had rejected.

III. Not all data should be considered as sensitive as current health data

Question 46. “Under what circumstances should unanticipated future analysis of data that were collected for a different research purpose be permitted without consent? Should consent requirements vary based on the likelihood of identifying a research subject?”

Answer. We are concerned about sections of the ANPRM that appear to treat all data as if they were biospecimens, like the provision that “the allowable current practice of telling the subjects, during the initial research consent, that the data they are providing will be used for one purpose, and then after stripping identifiers, allowing it to be used for a new purpose to which the subjects never consented, would not be allowed.”

Perhaps it would be appropriate to require consent for a novel use of a biospecimen, but we have trouble envisioning how this could be applied to political opinion polls, labor statistics, market research, and other such data. Not only scholars, but also politicians, marketers, and others outside of academia are constantly finding new uses for such data. These data are gathered by such diverse actors that we doubt the practicability of standardized consent language that would permit their use. Instead, we favor the free use of public data sets, as is the case now.

Question 54: Will use of the HIPAA Privacy Rule’s standards for identifiable and de-identified information, and limited data sets, facilitate the implementation of the data security and information protection provisions being considered? Are the HIPAA standards, which were designed for dealing with health information, appropriate for use in all types of research studies, including social and behavioral research? If the HIPAA standards are not appropriate for all studies, what standards would be more appropriate?

Answer. HIPAA’s prohibition of the use of geographic indicators is inappropriate for much non-medical research.

Under the proposal, research would qualify for the new excused category only if the researcher did not disseminate any of the 18 identifiers specified by HIPAA. Many of these identifiers, such as telephone numbers, license-plate numbers, and Social Security numbers, are the functional equivalent of personal names, so forbidding their use would not encumber research that seeks to offer anonymity to participants. But one category threatens mayhem: “All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocode . . .”

While the deidentification of geography may not burden medical research, it would render impossible a great deal of social-science research, ranging from ethnographic community studies to demographic analysis that relies on census tracts to traffic models based on zip code to political polls that report by precinct, not to mention studies conducted in countries with different systems of mapping. We fear that if geographic units as large as cities and counties are considered identifiers, an immense amount of

research—currently exempt—would be thrown into the expedited or even full-board categories, which is not the intent of this ANPRM.

Under 45 CFR 164.514(e)(3)(ii), a town, city, state, or ZIP code is not considered a “direct identifier[]of the individual or of relatives, employers, or household members of the individual.” We recommend that the Excused category take a similar position, and not require researchers to delete geographic units larger than a street from their data and reports.

***Question 59:** Would study subjects be sufficiently protected from informational risks if investigators are required to adhere to a strict set of data security and information protection standards modeled on the HIPAA Rules? Are such standards appropriate not just for studies involving health information, but for all types of studies, including social and behavioral research? Or might a better system employ different standards for different types of research? (We note that the HIPAA Rules would allow subjects to authorize researchers to disclose the subjects’ identities, in circumstances where investigators wish to publicly recognize their subjects in published reports, and the subjects appreciate that recognition.)*

Answer: Some HIPAA privacy protections are inappropriate for non-medical research.

The ANPRM suggests that “for research involving individually identifiable information, all biospecimens, and limited data sets, data security standards could require the use of reasonable and appropriate encryption for data maintained or transmitted in electronic form and strong physical safeguards for information maintained in paper form, audit trails, and access controls that allow only authorized personnel to have access to the information.”

This provision could place serious, undue burdens on researchers doing low-risk work. For example, what “strong physical safeguards” are available to the ethnographer living in a rural area of a developing country? Nor do we place much faith in the qualifiers that the data security encryption standards would only be “reasonable and appropriate.” Our experience with the present regulations is that IRBs overlook such qualifiers and are apt to insist on disproportionate levels of protection unless given clear instructions otherwise. We hope that regulators will allow scholarly organizations to develop standards for data protection, and that researchers who adhere to these standards be permitted to use the excused category.

***Question 63:** Given the concerns raised by some that even with the removal of the 18 HIPAA identifiers, re-identification of de-identified datasets is possible, should there be an absolute prohibition against re-identifying de- identified data?*

Answer. Just as individually identifiable census responses are made public after 72 years, so should all data eventually escape confidentiality requirements.

IV. The federal government should not regulate research it does not pay for

Question 71: Should the applicability of the Common Rule be extended to all research that is not Federally funded that is being conducted at a domestic institution that receives some Federal funding for research with human subjects from a Common Rule agency?

Answer. No.

In 2006, we recommended “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.” We and others hoped that this would allow them to try alternatives to the federal system of oversight.¹¹

We have mostly been disappointed. OHRP has noted a decline in the percentage of institutions voluntarily extending their FWAs to research not directly supported by HHS.¹² But it seems that most institutions that have not made the extension still insist on IRB jurisdiction for all their affiliates, so unchecking the box has not, as we had hoped in 2006, made life any easier for researchers.

Still, leaving institutions free to try alternatives for unfunded research could yet lead to innovation. We note that among the institutions not voluntarily extending federal authority to all research are some of the universities with the most innovative programs of human research protections: Ohio State University, the University of Michigan, the University of Pennsylvania, and the University of Texas. As Lisa Leiden of the University of Texas and—at the time—a SACHRP member explained in 2008,

We have talked about limiting the federal-wide assurances, unchecking the box, and I believe the position that we're going to be taking is to advocate in a gentle way thinking about doing that. We have heard both sides of the story or maybe just a few sides, but we think that there are certainly some advantages. And one of the advantages might be . . . what can we do with the expedited review level. It seems that there is a lot of flexibility in that, and we might be able to increase some of that by unchecking the boxes and adding different categories for that.¹³

We recommend, therefore, that the federal government concentrate on fixing the system for overseeing research that is funded while encouraging innovation for research that is not directly funded. Since, as the ANPRM concedes, the current system has serious flaws, it would be foolish to extend it to a much greater volume of research.

¹¹ “AAUP: Research on Human Subjects: Academic Freedom and the Institutional Review Board (2006)”; Malcolm M Feeley, “Response to Comments,” *Law & Society Review* 41, no. 4 (December 1, 2007): 811-18.

¹² Carol Weil, Lisa Rooney, Patrick McNeilly, Karena Cooper, Kristina Borrer, and Paul Andreason, “OHRP Compliance Oversight Letters: An Update,” *IRB: Ethics & Human Research* 32, no. 2 (2010): 1-6.

¹³ OHRP, “(SACHRP) July 15-16, 2008 Meeting,” n.d., <http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-08/index.html>.

We also repeat our 1981 observation that HHS conceded that no clear statutory authority exists for an extension of IRB oversight to research that is not directly funded by the Public Health Service. The statute has not changed since then.