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October 19, 2011

Jerry Menikoff, MD, JD  
Office for Human Resource Protections  
Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, Maryland 20852

*Submitted via electronic mail at <http://www.regulations.gov>*

Dear Dr. Menikoff:

Re: 76 FR 44512, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators," Docket ID – HHS OPHS 2011 0005

I write as President of the American Anthropological Association, the largest association of anthropologists in the U.S. and the world with 11,000 members representing all fields and subfields of anthropology. Our experts on the AAA Committee on Ethics have, at my request, analyzed the ANPRM very closely and prepared a detailed, analytical, and thoughtful response that I submit here. I urge you to consider it very seriously on behalf of the anthropological profession.

Sincerely yours,

Virginia R. Dominguez  
President, American Anthropological Association

Attachment

## **Comments on Proposed Changes to the Common Rule (76 FR 44512)**<sup>1</sup>

We applaud this effort by the Department of Health and Human Services and the Office of Science and Technology Policy to reshape the Common Rule (45 CFR 46) so as to ensure that human research participants are receiving appropriate protections. We agree with the authors of this Advance Notice of Proposed Rulemaking<sup>2</sup> that the current system has not been functioning as intended, resulting in burdensome oversight efforts that do not produce better outcomes for research participants.

The critical comments we offer below draw upon the insights of anthropologists working in diverse settings, from rainforest villages in Papua New Guinea to medical centers in the US. They reflect anthropologists' experiences as members of Institutional Review Boards (IRBs) and their considerable expertise about knowledge-making practices gained through anthropology's own disciplinarily distinctive methods of social analysis.<sup>3</sup>

There is wide recognition within our discipline that not everything an intellectually curious researcher might wish to do is ethically acceptable. Anthropology has a long history of commitment to the promotion of ethical practices: anthropologists are expected to adhere to codified norms of professional conduct;<sup>4</sup> and their professional associations have a proactive approach both to ethics education<sup>5</sup> and to the development of principled approaches to the ethical dilemmas of our practice<sup>6</sup>. Our comments are thus offered in a spirit of constructive engagement with the regulatory framework that currently governs much of our research.

### **Plan of this commentary:**

In addition to addressing questions posed in the ANPRM, we make two general Recommendations bearing directly on the achievement of its objectives:

**1. To more narrowly delimit the object of regulation:** In place of the present broad definition—"research" with "human subjects"—we recommend delimiting the regulatory object more specifically as "human experimentation" and/or "biomedical procedures" (see below for

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<sup>1</sup> In August 2011 the President of the American Anthropological Association, Virginia Dominguez, asked the Association's Committee on Ethics to study the proposed changes to the Common Rule and assess their impact on anthropological research. The present report is the result of this undertaking: It was jointly composed by Committee member Lise Dobrin and former Committee chair Rena Lederman, and submitted to the Association on the Committee's behalf.

<sup>2</sup> Hereafter ANPRM (that is, 76 FR 44512 entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators").

<sup>3</sup> E.g., Lederman 2007 Comparative 'Research'

(<http://onlinelibrary.wiley.com/doi/10.1525/pol.2007.30.2.305/pdf>); Lederman et al. 2006 Anxious Borders

(<http://onlinelibrary.wiley.com/doi/10.1111/amet.2006.33.issue-4/issuetoc>).

<sup>4</sup> <http://www.aaanet.org/issues/policy-advocacy/upload/AAA-Ethics-Code-2009.pdf>.

<sup>5</sup> E.g., <http://www.aaanet.org/publications/Ethicshandbook.cfm>.

<sup>6</sup> E.g., <http://www.aaanet.org/committees/ethics/bp.htm>.

definitions). Recommendation #1 is elaborated below (pp. 3-4) in our comments on “Part II” of the ANPRM.

**2. To rethink the proposed rulemaking strategy concerning “informational risks”:** We understand the need to free IRBs to focus on physical risk activities. However, segmenting out “informational risks” for mitigation through a process modeled on the Health Insurance Portability and Accountability Act (HIPAA) regulations would be disastrous for social and humanities research, including anthropology. Recommendation #2 addressing the question of informational risks is elaborated below (pp. 21-22) in comments on “Part V” of the ANPRM.

We understand that after an orienting discussion (76 FR 44512-13), the ANPRM identifies seven “areas of concern” around which criticisms of the current human subject regulations have been raised and summarizes seven related proposals for changes (76 FR 44513-14). Moving through each proposal in turn, it offers more detailed discussions of the current rules, the relevant criticisms, and the proposed changes. We further understand that public commentary is being solicited specifically in the form of responses to the ANPRM’s numbered questions.

Nevertheless, we are concerned that simply responding to the questions will have the effect of diffusing and decontextualizing our commentary. Just as context and framing are necessary for the public’s understanding of this proposed rulemaking, context and framing are also necessary for HHS/OSTP rulemakers’ understanding of this commentary.

Therefore throughout, before responding to specific questions as requested, we begin with orienting paragraphs. We begin immediately below with an analysis of the problem that this ANPRM addresses and our first general Recommendation.

## **II. Ensuring Risk-based Protections (76 FR 44514-21: Part II, Questions 1-28)**

Like the proposed changes, the existing Common Rule makes an effort to calibrate levels of review with levels of risk. Over time, however, the workloads of IRBs have expanded to such an extent that they cannot focus adequate attention on the kinds of higher risk research that motivated the creation of HS protections in the first place.

The ANPRM diagnoses this expansion as primarily the result of the ballooning volume and diversity of research. In contrast, we diagnose it as primarily the result of vague and general regulatory definitions applied in an adversarial environment. The vagueness and generality of the regulatory object invites ever-broadening and variable interpretations by IRBs, which are understandably cautious lest their decisions fail to pass muster with federal auditors. Thus, when faced with an all too uncertain choice to “exempt” an activity or to do an “expedited” or “full convened IRB review”, boards have tended to opt for the full review rather than take the chance of overlooking harms to research subjects and creating problems for their institutions (a response many critics tag “mission creep”).

In the existing regulations, guidance in the form of lists has been the main means for helping IRBs and administrators make choices (a strategy mirrored at the local IRB level in excessively long, micro-managed applications and consent forms). However, in the absence of a principled rationale, creating and adjusting lists (e.g., of investigational techniques like “surveys”, “focus groups”, “oral history” et al.) promotes anxiety for researchers and IRBs alike. List-making results in a welter of qualifications and addenda that engender freshly conflicting interpretations and further caution-motivated full board reviews.

At the root of this dynamic, we believe, is an inadequately delimited object of regulation (especially 45 CFR 46.102d, “Research”). We argue that without a tighter and more principled definition of the regulatory object, the proposed rulemaking will be susceptible to the same caution-driven decision-making that has overburdened IRBs, undermining the quality of their work and inviting widespread criticism from researchers.

### **Recommendation #1**

We therefore recommend a revised definition of what 45 CFR 46 regulates, together with a related rethinking of the present mode of clarifying exemptions (or excusals) and risk distinctions (with their corresponding levels of review): that is, 45 CFR 46.102 and 45 CFR 46.101(b)(2); and 76 FR 44516-17: II(B)(2)(a). We take our lead from the ANPRM itself, which indicates a willingness to narrow the definition of what is to be regulated (e.g., 76 FR 44521, Q 24). The revised definition below preserves quite a bit of the current guidance while reorienting it explicitly around the rationales that motivated human research protections historically. In returning to the foundational goals of human research ethics regulation, we build upon the ANPRM’s recognition of a qualitative distinction among different kinds of risks (76 FR 44515-16: II(A)): particularly, the association of “physical” risks with a likelihood of “more-than-minimal” harms and the reassignment of “informational” risks to an alternative means of oversight.

**Whereas the Common Rule currently applies to “research” involving “human subjects” (45 CFR 46.102d, f), we recommend 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.**

Human experimentation involving systematic withholding of information and, particularly, instances of biomedical research that caused actual physical harm (e.g., the activities of Nazi concentration camp doctors, the Tuskegee syphilis study) were central to the rationale that originally prompted the promulgation of 45 CFR 46 and establishment of IRBs.

A mechanism for determining whether a research protocol would be subject to review could be incorporated into the proposed “registration” procedure involving a one-page form, outlined in the proposed rulemaking (76 FR 44515 (4)(i)). That form could directly ask registrants whether their planned work involves (1) biomedical procedures that involve physical interventions or that might pose the risk of physical harm to potential participants; or (2) the withholding of information or active deception of potential participants as an element of experimental study design.

This innovation would greatly simplify the decision-making process presently necessary to distinguish “minimal” from “greater than minimal” risk and “expeditable” from “full board” review (a focus of 76 FR 44514-21: Part II): these decisions would now pertain to two well-defined types of studies that qualify for review. Sorting expeditable biomedical and experimental research from that requiring full board review would be a much more manageable and less speculative task.

Meanwhile, non-experimental, non-biomedical studies would no longer need to be exhaustively enumerated (as in 45 CFR 46.101(b))—a hopeless task. Posing neither potential “physical” risks nor the “psychological” risks associated with deception, they would all (in the terms employed in the ANPRM) be “registered” and “excused” from IRB review, but subject to appropriate protections for “informational” risks (e.g., breaches of confidentiality).

As to the proposed category of “psychological” risk: We believe that it is a slippery, inherently subjective concept and should be dropped. It is likely to become a fresh source of uncertainty and overly cautious reviewing, thereby undermining the point of this proposed rulemaking. In fact, we doubt that the “psychological” is a distinct type of risk: instead, it is best construed as a subjective (experiential) quality associated in various ways with the risk of “physical” or “informational” harm. The latter two are more amenable to objective definition.

As to appropriate protections for “informational” risks, see our comments on “Strengthening Data Protections to Minimize Information Risks” (pp. 18-25) and Recommendation #2 (pp. 21-22).

**In summary:**

We contend that the vagueness of the key regulatory definitions is a key cause of the relentless expansion in the workload of IRBs. This problem is not addressed in the proposed rulemaking. Unfortunately, thirty years of IRB practice guided by the current regulations have encouraged habits of thought construing an indefinite, globally inclusive concept of “research”

with suspicion as inherently dangerous. This stance contributes to IRBs' inability to make the critical distinctions that are necessary for an effective focus on higher-risk activities.

Recommendation #1 proposed above addresses this fundamental problem by reversing the current strategy for deciding how activities are or are not deemed within the purview of the Common Rule. The current strategy defines the object of IRB review relatively generally and then labors to identify and enumerate specific methodologies or types of study eligible for "exemption" or "expediting": experience has shown that this opt-out reviewing strategy engenders endless qualification and argument. In contrast, our Recommendation #1 defines the regulatory object more specifically and then presumes unnamed activities to be exempt or "excused": this default-out reviewing strategy promises greater clarity for investigators and IRBs alike.

Beyond these consequential practicalities, there is a philosophical value in excusing activities that do not meet tightly defined criteria historically associated with higher-risk research. Such a move grounds the IRB decision model on the ethical rationale that originally prompted human research ethics regulations and that remains salient today.

Our comments on questions associated with 76 FR 44514-21 (Part II "Ensuring Risk-based Protections") follow:

**"Calibrating Levels of Review to Level of Risk" (76 FR 44516-18, sections B1&2, Q 1-13)**

**Q 1**

We support all changes that increase the clarity and specificity of regulatory definitions. Unfortunately, the current definition of "minimal risk" (45 CFR 46.102(i)) is ambiguous and the examples provided are not (and cannot be) comprehensively helpful. We illustrate the point by reference to sociocultural anthropologists, who have had persistent difficulty locating their most characteristic research activity, "participant observation", relative to this definition.

Participant observation involves living explicitly as a researcher among the people whose circumstances we seek to understand, conversing with them in their own language, fitting in to their rhythms of life, participating with them in those activities to which we are invited, and abiding by our hosts' preferences with regard to note-taking and other forms of recording. Participant observation contrasts with interviewing and conventional experimental procedures insofar as it does not involve extracting participants from their normal social settings. Participant observation also contrasts with "field experiments" and "covert observation" (or "undercover" research): while the latter two methodologies are also carried out in the participants' normal social settings, unlike anthropological participant observation they depend for their validity on limiting or controlling the information available to participants.

Because participant observers do their research in their consultants' own environments, rather than in settings where the researcher holds the control, and because the validity of their data does not depend on withholding and controlling information, "the probability and magnitude of harm or discomfort anticipated in" participant observation "are not greater in and of themselves than those ordinarily encountered in daily life".

Although participant observation would appear to fit the current definition of “minimal risk”, it has (as far as we know) never been mentioned in lists of “minimal risk”, “exempt” or “expedited” research activities. Anthropologists find themselves having to make the case anew each time their work is reviewed. Definitional clarity is always at risk so long as it depends on the explicit naming and listing of included and excluded activities.

One additional point by way of clarifying the definition of “minimal risk”: The “daily life” standard defining “minimal risk” in 46.102(i) currently implies acceptance of socially normal or culturally expected controls on the flow of information. For example, politeness, kindness (“white lies”), shyness, and enactments of conventional social roles are all quite appropriately understood as meeting Common Rule criteria of “minimal risk”. The definition of “deception” that we offer in Recommendation #1 (pp. 3-4) and in our comment on Q 17 is meant to exclude these daily life practices: as here defined, “deception” specifically includes only those controls on the flow of information considered by the relevant scholarly community as necessary methodological conditions for the collection of valid data (e.g., withholding study hypotheses or aims from participants).

**Q 2**

We support the proposed limitation on continuing review in “minimal risk” cases.

**Q 3**

We support the proposed rulemaking with respect to the continuing review of “the remaining study activities” if the latter “only include those that could have been approved under expedited review” or that would qualify as “excused”.

**Q 4**

We strongly support the proposed rulemaking: considering only “reasonably foreseeable” physical risks makes sense insofar as it encourages IRBs to take the proposed “excused” category seriously. Allowing reviewers to anticipate risks beyond those that are “reasonably foreseeable” invites projection and unwarranted constraints on academic freedom.

**Q 5**

This question asks for comments concerning criteria needed to pin down degrees of “psychological” risk: we strongly support eliminating this category altogether. As noted above (p. 4), “psychological” risk is a slippery, inherently subjective concept. As such, it is likely to become a fresh source of uncertainty and cautious reviewing, thereby undermining the point of this proposed rulemaking. In fact, “psychological” risk may be better understood not as a distinct type of risk but rather as a subjective (experiential) quality associated in various ways with the risk of (more objectively specifiable) “physical” or “informational” harm.

**Q 6**

We believe that efforts to attach levels of risk to nonphysical interventions (e.g., survey instruments) in the abstract are fruitless, as their risks always depend on context. Our expertise in cross-cultural research further leads us to view as fruitless efforts to specify across-the-board “types of questions” or topics (e.g., sexuality) as inherently “greater than minimal risk”. The

riskiness of topics or questions can only be established in light of the particular context and local cultural or sub-cultural norms. For this reason, we believe that the ANPRM's effort to predetermine offensive or risky topics is inherently flawed. Likewise with categories of vulnerable persons: indeed, even reference to "children" and the like only make sense in light of particular conditions and local cultural conditions. The Common Rule specification of "vulnerable populations" may make sense in most situations in the US, but may not make sense in other settings where social categories may differ (e.g., where the relevant distinction may be ritually initiated vs. uninitiated boys).

**Q 7**

This question asks whether various biomedical procedures qualify for expedited review. We are not subject matter experts on these procedures. However, as our response to Q 6 implies, biospecimens are accorded varying meanings depending on local cultural standards and notions of personhood (see also our responses to Q 47-53, pp. 17-18, and Part V below). To the extent that research increasingly occurs in international and cross-cultural contexts, we must take care not to assume that our cultural standards are universal.

**Q 8**

We believe that any form of human experimentation that involves actively exposing people to radiation should be considered potentially risky and hence subject to full board review. The National Academy of Science Committee on the Biological Effects on Ionizing Radiation (the "BEIR Committee") has periodically reviewed the literature and issued consensus reports. Rejecting the notion that there is a certain level of exposure to radiation that causes no harm, BEIR V (1990) acknowledged that there is no threshold effect, meaning exposure to ionizing radiation at any level generates an adverse effect on cellular activity, with exposure risks for children estimated at twice that of adults. BEIR VII (2005) reaffirmed the 1990 conclusion that every exposure to radiation produces a corresponding increase in cancer risk.<sup>7</sup>

**Q 9**

This question asks about the best frequency for updating the lists of activities that allow for expedited review. As noted on pp. 2-5 and in Q 1 above, the "list-making approach" to issuing guidance is necessitated by an over-general definition of the regulatory object. This arrangement is neither coherent conceptually nor workable in practice. The list-making approach is unworkable because of the inherent variability and context-dependence of risk. We view a "systematic, empirical assessment of the levels of risk" as impractical and do not believe that it "would provide greater clarity about what would be considered to constitute minimal risk" (76 FR 44516 (2) (i)). Recommendation #1 (pp. 3-4 above) advocates a decision strategy that is based on a targeted definition of what is under review: study activities involving physical interventions (e.g., biomedical science) and human experimentation (e.g., behavioral science).

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<sup>7</sup> National Academy of Science. 2005. BEIR VII: Health Risks from Exposures to Low Levels of Ionizing Radiation. Washington DC: National Academy of Science Press.

**Q 10**

This question concerns which of the current review criteria should not apply to expedited research. In our view, the approach to review laid out in 45 CFR 46.111 is flawed in more basic ways, insofar as it builds on a vague and ambiguous definition of “research”. For example, several of its parts (e.g., 111(a)(1) “sound research design”; 111(a)(2) “importance of the knowledge that may reasonably be expected to result”) imply standards of evaluation that may appear universally applicable but are actually particular to certain scientific fields as opposed to humanistic ones. While research in oral history or sociocultural anthropology also requires “sound research design”, what that involves may be quite unlike that required for biomedicine or experimental psychology.

Reference to “designed” and “generalizable” in the current definition of “research” implies methodologies involving experimentation familiar in biomedicine. However, because this more precise sense is not explicit, both IRBs and researchers interpret it broadly. For example, even though their modes of planning differ from the experimental designs that IRBs expect, folklorists, interpretive sociocultural anthropologists and the like consider what they do to be research (in their respective disciplinary senses), present it as such to their IRBs, and are therefore advised by IRBs to submit applications. However, when they do so, their protocols are evaluated as “poorly designed”: as bad research, rather than simply not “research” (in the present regulatory sense).

A narrower, more precise definition of the regulatory object would make the current review criteria for expedited research in 46.111 meaningful. They would apply explicitly and specifically to biomedical and behavioral science study procedures, excluding non-biomedical, non-behavioral science fields, which have qualitatively different conventions of research practice and correspondingly distinct standards for evaluating quality and ethics. If these other fields are to be reviewed, then an appropriate system needs to be designed for them: see our Recommendation #2 (p. 20-21 below; see also our response to Q 25).

**Q 11**

We agree that research should always be reviewed by someone who is “appropriately trained”. However, we seek affirmation that reviewers be knowledgeable not only about regulatory principles but also about the research methodologies being reviewed. This is particularly relevant given the diversification of research, as outlined in 76 FR 44512-3.

In practice, the guidance (45 CFR 46.107) that reviewers be “appropriately trained” is not always followed. Anthropologists preparing to engage in participant observation routinely experience review of their protocols by board members who lack expertise in the standard methods anthropologists employ (see response to Q 1 above). This situation has demoralized individual researchers and encouraged widespread cynicism about the value of regulatory oversight.

Of course, we recognize the importance of establishing review procedures and appeal panels that minimize the potential for professional or personal conflicts of interest. However, many institutions manage to achieve this in the context of disciplinarily appropriate review. We should look to such institutions for models of good practice.

Finally, while the current regulations are meant to ensure that board membership is methodologically diverse, the rules for expedited review (45 CFR 46.110) do not similarly

ensure this because the need for the reviewer to have methodological as well as regulatory expertise is not specified. While we understand that the current regulations do not allow for protocols to be disapproved through expedited review, our colleagues have reported that many rounds of requests for clarifications and changes can be as discouraging as outright disapproval.

**Q 12**

This question asks for advice concerning what adjustments to protocols, consent forms, and other documentation might reduce the burdens on researchers without decreasing protections for subjects. Generally, we support efforts to trim down key documentation: models might be solicited from institutions that have successfully streamlined their documents. However, we do not support moves that require standardized forms, since that kind of rigidity undercuts the positive benefits of the local control model on which IRBs are based.

**Q 13**

We are neutral on these questions.

**“Moving Away From the Concept of Exempt” (76 FR 44518-21, section 3 ff, Q 14-29)****Q 14**

We strongly support the proposed expansions in the range of studies that would qualify for the “Excused” category and do not see them as likely to “discourage individuals from participating in research”. More precisely, we believe that the Belmont standards (“respect for persons, beneficence, justice”) will be enhanced by basing the “Excused” category on the clarified distinction between “physical” and “informational” risk proposed in the ANPRM and further developed above (pp. 3-4). The current strategy for specifying “Exempt”/“Excused” activities by means of lists is necessitated by an over-general definition of what is to be reviewed. As noted in several places above, we recommend instead clearly and precisely defining what is under review (human experimentation and research involving physical risks) and explicitly “excusing” all unnamed activities (see our Recommendation #2 in section V below regarding alternative modes of review).

**Q 15**

There are indeed types of studies that should qualify for the “Excused” category but that are not mentioned anywhere in either 45 CFR 46 or the proposed rulemaking. One such instance is participant observation, sociocultural anthropology’s distinctive research method (described at length in our answer to Q 1 above, where we also explain why it qualifies as “minimal risk”). Participant observation is not equivalent to “interviewing”, “oral history”, “focus groups” and other activities named in the present and proposed rules. If the new rules retain the current definition of “research”, we support inclusion of “participant observation” and “observation” in the “Excused” category. However, we recommend adopting a more precise definition of what is being regulated (human experimentation and study procedures involving physical risks to participants). Doing so would obviate the need for listing “Excused” activities in the first place.

**Q 16**

This question concerns whether it makes sense to “excuse” research involving “surveys and related methodologies” only if they avoid certain “emotionally charged topics”; and if so, “what entity should be responsible” for making that determination. First, we emphasize that the term “related methodologies” is inadequate: the proposed rulemaking offers no principled approach to creating that grouping or interpreting that phrase. Second, as noted elsewhere (e.g., Q 6, Q 7), the sensitivity of topics cannot be gauged apart from specific social and cultural contexts.

**Q 17**

This question asks whether studies can be “excused” if they involve deception, adding parenthetically “and if so, how should deception be defined?” Recommendation #1 (pp. 3-4) addresses the question pragmatically and at length (see also our response to Q 1). We support continued IRB review of all studies that use deception systematically as a necessary condition for the production of valid, credible data. In that context, deception can be defined as “limiting or controlling the information available to research participants either by withholding information about the study topic and procedures and/or by actively proffering misinformation”. Examples are offered in Recommendation #1, above.

As noted above (Q 1), our definition of “deception” is meant to exclude behaviors associated with the “daily life” standard defining “minimal risk” (46.102(i)). That is, “deception” as defined in this comment does not include socially normal or culturally expected controls on the flow of information (e.g., politeness, kindness, shyness, and conventional social roles): Common Rule criteria for establishing “minimal risk” quite appropriately tolerate these behaviors. The definition of “deception” proposed here specifically includes only components of research methodology considered by a relevant scholarly community to be necessary for the collection of valid data.

**Q 18**

We are neutral on this question, which doesn’t pertain to anthropological research.

**Q 19**

We strongly support the idea that researchers who are engaged in “excused” research adhere to a “brief (i.e. no more than one week) waiting period” before commencing with their project. Our emphasis here is on “brief”: given that anthropological research often takes place internationally, involving complex travel arrangements and extended residence in locations that lack standard academic infrastructure, long and indeterminate waiting periods would impose a particularly heavy (and potentially costly) burden on researchers.

**Q 20**

We prefer the term “Registered” to the proposed term “Excused” (or the existing term “Exempt”) because it captures the proposed rulemaking more accurately. However, we are strongly opposed to subjecting “registered” work to the model for protecting participants proposed in 76 FR 44524 Part V (see below).

**Q 21**

This question concerns whether institutions accepting federal funds should be required to conduct retrospective audits of some percentage of “Excused” studies to ensure that they truly qualify as such (and, if so, then by what method, percentage, etc.). We strongly support the existing local model of IRB process on the assumption that institutions are best qualified to determine their own auditing procedures. See our response to Q 66 below.

**Q 22**

We strongly support the proposed plan to move away from prior review of all research, relieving IRBs of a burden that undermines their ability to focus on higher risk activities. We support retrospective assessments only as long as they are controlled by local institutions in the ways they determine to be most appropriate.

Note, however, that audits will only serve the interests of research participants if the criteria for “Excusal” (or “Registration”) are clear. On pp. 3-4 above we outline one strategy for achieving such clarity: Recommendation #1 makes it possible for institutions to confidently monitor the research carried out under their auspices, while providing researchers with clear guidelines for avoiding ethical breaches. Under the clearer conditions we propose, we believe that researchers would indeed “possess the objectivity and expertise to make an initial assessment of whether their research qualifies” as “Excused”. We also believe that a one-page registration form would suffice (see the “procedural mechanism” outlined on p. 4) without compromising participant protections.

**Q 23**

This question asks about the circumstances under which it should be permissible to waive consent for research involving “existing data and biospecimens.” We find the phrasing of this question extremely troubling as it reveals a lack of distinction between the very general concept of “data” with the very specific notion of “biospecimens”. So long as the framing of ethical regulations continues to take for granted a model of research in which “biospecimens” are the prototypical form of “data”, there is no hope of achieving a reasonable, efficacious regulatory system. Please see our response to Questions 45 – 53 below.

**Q 24**

We are neutral concerning Quality Assessment and similar activities. We do strongly support changes in the current definition of “research” (referred to on 76 FR 44521) as described in Recommendation #1 above (pp. 3-4): consequently, we strongly oppose adopting “the distinction made in the HIPAA Privacy Rule (45 CFR 164.501(1))” insofar as that distinction hinges on the current Common Rule definition of research (see also our responses to Q25, Q26, and Q10).

**Q 25**

We are strongly opposed to the association/dissociation of whole fields of study (e.g., history, literature) with Common Rule coverage (and with “generalizable knowledge” in particular): All social and humanistic research can be described as “designed to develop or contribute to generalizable knowledge” (see our response to Q 10).

Some disciplines or parts thereof are conventionally deemed “particularizing” because their research processes focus empirically on local cultures (like sociocultural anthropology), on precisely identified persons and events (like history and journalism), or on individual literary figures (like English or French literary studies), and the like. In this they may be distinguished from the physical sciences, which conventionally de-emphasize particulars. However, no so-called particularizing field pursues its local studies as ends in themselves. Historiography ceased being “chronicle” centuries ago (how else would it be possible to speak of “the lessons of history”?); anthropology does not simply document folklore (indeed, even the discipline of Folklore Studies is no longer content to do that), and insofar as editorial opinion and news analysis have been situated next to straight news reporting in recent years, the distinction between description and interpretation has even been blurred in journalism.

By raising this obvious problem, we are absolutely NOT implying that we think that historians and literary scholars ought to be covered under the Common Rule (or, conversely, that sociocultural anthropologists, along with these others, ought to be freed of all ethics oversight). On the contrary: their work is already subject to libel and slander laws, not to mention the ethical strictures of their respective disciplines.

Instead, what we are trying to emphasize is that these distinctions are not germane to the key problems that prompted the regulation of human research in the first place. If our concern is to identify “risks” to human research participants, then generalizable/not-generalizable is not a useful diagnostic for distinguishing reviewable from not-reviewable research. Literary scholars and historians write biographies that transform private individuals into public figures and shape their reputations (not infrequently for the worse) whereas survey researchers typically anonymize their respondents since their research questions concern social trends and mass phenomena. Nevertheless, survey researchers, but not biographers, have been made subject to the Common Rule. Clearly, “generalizability” has not proved a helpful resource for comparing the relative risks of these activities.

#### **Q 26**

We support changes that result in clarity. In that vein, as our responses to Q 25 and other items have asserted, clarifications of particular exclusions or exemptions—in this case, Exemption category 5—will not hold without a more basic revision of the definition of that from which these items are being exempted or distinguished. We will always have trouble distinguishing particular activities, like demonstration projects, from “research” as presently defined because they can always be construed as potentially “generalizable” or “broad”.

#### **Q 27**

We strongly support the current interpretation of 45 CFR 46.111(a)(2): IRBs should be restricted to reviewing risks pertaining to participation in the research itself; they should not assess risks related to a study’s possible long-range effects. Suppression of potentially “disagreeable” research results in research is indistinguishable from censorship and therefore a violation of basic speech protections necessary in a healthy democracy.

The research world is rife with projects whose results bore, interest, annoy, please, anger, or enlighten research participants (just as they do fellow researchers). This world is not generically the people’s enemy. On the contrary, those of us working in US colleges,

universities, news media, and research institutions have inherited traditions of free inquiry whose continuation is vital to this country's political, economic and social life. It would be deeply ironic if a regulatory system put in place to protect human beings were transformed into a device focused on restricting their power to know the world.

**Q 28**

We strongly support the proposed rule change: the Common Rule should "include a requirement that every institution must provide an appropriate appeal mechanism". What is more, that appeal mechanism should "be available for appeals asserting that the investigation ... does not require IRB approval."

**Q 29**

We support a rule change increasing transparency: IRBs should identify all actions it takes that are not required by the regulations.

**III. Streamlining IRB Review of Multi-Site Studies (76 FR 44521-22: Part III, Questions 30-34)**

We have no specific comments on Q 30 – 34. However, we do wish to respond to the discussion in this section in a general way. As should be clear from our answers to Q 1 and Q 19 above, much anthropological research is conducted in a geographically and institutionally "distributed" manner. Anthropologists regularly conduct field research in communities and organizations away from their home institutions, both domestically and abroad. Under the current regulations they need local IRB approval, which is generally contingent on prior approval by an appropriate authority controlling access to their field location(s): a national, regional, or local authority of some sort; indeed, often more than one. These are not always dedicated Ethics Boards, though they typically concern themselves with ethical aspects of the proposed research. Anthropologists do this not just because it is necessary for IRB approval, but because it is a disciplinary standard to be "alert to proper demands of good citizenship or host-guest relations" and to be "honest and candid" with one's "own government" and with "host governments".<sup>8</sup>

We also reiterate our conviction that local knowledge is a critical resource for ethical decision-making in culturally and geographically disparate situations. This is as true with respect to IRB deliberations as it is in any other circumstance. Over time, individual boards develop detailed, experience-based knowledge of the research being done at their own institutions. They learn which researchers, laboratories, etc. are ethically conscientious and which have historically raised concerns. One insight we can take from the Presidential Bioethics Commission's recently released report on the STD research carried out in Guatemala in the 1940s is that there is overlap between the institutions and individuals who engaged in these

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<sup>8</sup> AAA Code of Ethics 2009, III and IIIC(2): <http://www.aaanet.org/issues/policy-advocacy/upload/AAA-Ethics-Code-2009.pdf>; see also <http://www.aaanet.org/cmtes/ethics/Ethics-Resources.cfm>.

human subjects violations and those who engaged in the unethical Tuskegee syphilis studies.<sup>9</sup> The report concludes that the researchers' willingness to defy ethical norms and regulations developed as a "culturally induced moral ignorance" within a "small and coherent professional network". It would be regrettable not to seek the locally particular knowledge of such professional networks that institutions have gained through practical experience over time.

#### **IV. Improving Informed Consent (76 FR 44522-24: Part IV, Questions 35-53)**

We strongly support rule changes that facilitate participants' ability to give truly informed consent. That is why Recommendation #1 above 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.

#### **"Improving Consent Forms" (76 FR 44523 section A, Q 35 – 40):**

We strongly endorse proposals for making consent forms shorter and more accessible (76 FR 44523, section A). However, while we support "making available standardized consent form templates" (section A(6)) to model good practice, we do not endorse proposals to prescribe format and content insofar as this could prevent researchers and IRBs from applying their locally and experientially honed judgment. This is a problem that affects anthropologists disproportionately, as they so frequently work in contexts where linguistic and cultural conventions differ from those presupposed by the framers of the regulations. While we were preparing these comments, one anthropologist mentioned to us that she was forced to model her consent documents for classroom observations and interviews on forms designed for medical interventions such as intubation. Her IRB prevented her from adjusting her consent forms—using language that would be clear and pragmatically appropriate for the study population—to facilitate truly informed consent. We must recognize that foreign participants can be baffled and overwhelmed by procedures that Americans take for granted, such as "initialing" a line.

#### **Q 35**

On factors contributing to excessive length and complexity of consent forms, our analysis (pp. 2-3) is part of our more general diagnosis of the factors explaining the IRB work burden. We support streamlining consent forms and taking any other measures that will allow IRBs to cease micro-managing their documentation in order to avoid risks to their institutions.

#### **Q 39**

We are opposed to the use of the HIPAA Privacy Rule as the authorizing framework for anthropological research and therefore have no comment on questions about how other changes might be brought into alignment with that change.

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<sup>9</sup> See "Ethically Impossible" STD Research in Guatemala from 1946 to 1948  
<http://www.bioethics.gov/cms/node/306>.

**Q 40**

We agree about the importance of disclosing financial relationships between investigators and study sponsors to research participants (a principle also affirmed in the AAA Code of Ethics).

**“Waiver... or Documentation of Informed Consent in Primary Data Collection” (76 FR 44523 section B, Q 41-44):**

We strongly support the proposed rule change with regard to “waivers of informed consent” (76 FR 44523), which acknowledges that while 45 CFR 46.117(c) allows for waivers of signed consent forms, the conditions may not be flexible enough for “research conducted in an international setting where for cultural or historical reasons signing documents may be viewed as offensive and problematic”. This is also the case in some domestic settings.

However, as noted elsewhere (e.g., p. 3), the listing of non-experimental, non-biomedical techniques and methodologies is a flawed device for clarifying guidance in this ANPRM (e.g., Q 44), in 45 CFR 46 (e.g., 46.101(b)(2)), and on HHS’s “Categories of Activities”.<sup>10</sup> For example, the passage cited in the previous paragraph goes on to point out that “studies that only involve surveys, focus groups, and interviews with competent adults” won’t need documentation waivers because, under the proposed rule changes, they would qualify as “Excused” and require only oral consent.

First, such lists pose significant interpretive challenges for IRBs. They engender cautious over-regulation, provoking consternation among researchers, who cannot understand how any number of unnamed activities differ ethically from those that happen to be named. For example, existing lists include activities familiar to marketing researchers (e.g., taste-testing) but regularly omit mention of activities familiar to linguists, anthropologists, and others (e.g., conversation analysis, elicitation of grammaticality judgments, participant observation). The “human subject protection” rationale for these omissions is obscure: one suspects that they may simply be unfamiliar to the list authors.

Second, such lists are confusing to researchers and IRBs because different disciplines use methodological terms (e.g., “interview”) differently. Additionally, as the ANPRM itself notes, because research methodologies are dynamic, any enumeration of techniques is likely to need endless adjustment. The ANPRM indirectly acknowledges this problem when it ends its lists with the phrase “...and [other] similar procedures”: see 76 FR 44513, 44515, 44518, 44519, 44523.

**Q 41**

Of the four waiver criteria cited in 45 CFR 46.116(d), #3 pertains to research that cannot be carried out without withholding information from research participants. Recommendation #1 (pp. 3-4 above) implies that such research would be “excused”. Because prior informed consent

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<sup>10</sup> See <http://www.hhs.gov/ohrp/policy/expedited98.html>.

is never fully possible in credible human experimentation research designs, a review would help protect participants' interests during the research and encourage adequate debriefing afterwards.

**Q 42**

We do not endorse a checklist approach to the elements of oral consent. The content of oral consent needs to be tailored to the social and cultural context of the research community if it is to be truly informative and meaningful. Understanding this context is often one of the key goals of anthropological field research. For this reason at least, oral consent in anthropological fieldwork is not an "event" (e.g., listening to a script and agreeing to some or all of its terms). Most anthropologists assert that meaningful consent is a process that researchers need to attend to in an ongoing way over the course of research: this principle is explicit in the current (2009) AAA Code of Ethics, which states that "the informed consent process... should be initiated in the project design and continue through implementation by way of dialogue and negotiation with those studied."<sup>11</sup>

**Q 44**

As noted above, we do not recommend a list approach to determining which research activities are or are not appropriate for oral or written consent. Instead, Recommendation #1 (pp. 3-4 above) is that all methodologies that are not experimental (i.e., not dependent on deception) and not biomedical (i.e., not involving "physical" risks) be "Excused" from IRB review and therefore be free to obtain informed consent orally in context-sensitive and culturally particular ways: that is, not according to a pre-planned script but in conversation with research participants.

**"Consent Protections Related to Reuse or Additional Analysis of Existing Data and Biospecimens" (76 FR 44523-4 section C, Q45-53)**

We strongly object to two related assumptions upon which these proposals are based: First, "biospecimens" are not simply a type of "data" (as *The Immortal Life of Henrietta Lacks*, cited on 76 FR 44524, makes clear: see comment on Q 47-53 below).

Second, even excluding biospecimens, the category "data" does not have a unitary meaning across disciplines. For example, humanistic social studies do not produce "data sets" rigidly distinguishable from data analysis and interpretation, as court arguments over the evidentiary status of subpoenaed ethnographic fieldnotes or historians' testimony make clear. Our responses to Q 45-46 elaborate this point.

**Q 45**

This question pertains to consent for future research uses of data initially collected for "non-research" purposes. In medical contexts, it is clear that "data initially collected for non-research

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<sup>11</sup> AAA Code of Ethics (2009) Section A(4) <http://www.aaanet.org/issues/policy-advocacy/upload/AAA-Ethics-Code-2009.pdf>.

purposes” refers to personal biomedical/health information collected in the course of individual medical care (therapy). Monitoring the therapy/research distinction makes principled sense in light of the key abuses (e.g., the Tuskegee study) that motivated 45 CFR 46. However, outside of biomedical contexts, the meaning of “data initially collected for non-research purposes” is not similarly meaningful and clear.

Like this ANPRM wording, the current regulations do not distinguish between humanistic and biomedical/behavioral science methods and records: on the contrary, they presuppose an unjustified conflation of heterogeneous types of “research” and, therefore, of heterogeneous types of “data”.

For example, taken literally, the wording of this question is directly applicable to historiography, which accords special credibility to the study of records collected (often by interactions with persons) for purposes unrelated to that of the investigator. To require consent in such a case “based on the likelihood of identifying the research subject” would cause IRB (or HIPAA Privacy Board) workloads to rise dramatically and historical scholarship to grind to a halt. Historical scholarship is conventionally presumed exempt or excluded from “human subjects research” review; however, if we take this regulatory language seriously, we need to ask “by what principle?” and “to what other research practices ought that principle apply?” Principled distinctions need to be established: that is the point of Recommendation #1 (pp. 3-4).

#### **Q 46**

With respect to consent for “unanticipated future analysis of data that were collected for a different research purpose”, one needs to consider how this might apply (or not) to historians and other humanists. To brush this query off by pointing out that historical research is not conventionally reviewed by IRBs simply evades the need to clarify the relevant principle. After all, historians and literary scholars (who are not conventionally reviewed) and anthropologists (who are) all rely on secondary sources written by other scholars on the basis of those authors’ primary (e.g., archival, field) research. Any rulemaking relating to “consent” necessary for “unanticipated future analysis of data that were collected for a different research purpose” needs to make a meaningful distinction between fields of study. That is the point of Recommendation #1 (pp. 3-4).

#### **Q 47 – 53**

These questions all concern conditions for consent to research using biospecimens collected for “non-research”—we infer (as in Q 45, Q 46), therapeutic—purposes. In particular, they concern the ethics of generalized consent in such cases, which would greatly facilitate important biomedical research (see also our response to Q 45 and Q 7). In this context, we caution that biospecimens cannot be considered simply as “information” (identifiable or otherwise). Both in American culture (e.g., descendants of Henrietta Lacks) and overseas, biospecimens like blood or DNA can also carry meanings associated with distinctive “personhood”, family relationships, cultural identity and property, and the like. Insofar as this pertains to the Belmont principle of “respect” rather than “beneficence”, the ANPRM’s move toward a solely “risk-based” approach to research ethics is not likely to provide adequate guidance.

Nor are biospecimens unique in being “data” (values detachable from their particular sources) for scientists while also being intimate emblems of personhood, family, cultural

identity and the like for ordinary people: objects of all kinds may function as evidence for researchers but personal or cultural symbols for laypeople. For example, anthropological archaeology and paleoanthropology (subfields specializing in the interpretation, respectively, of the material remains of human social life and of the evidence for hominid evolution) are not typically subject to the Common Rule because their investigations do not typically necessitate interactions or interventions with human subjects. Nevertheless, archaeologists and paleoanthropologists are acutely aware that objects of all kinds—not only human remains but even stones and heaps of dirt—can produce strong feelings of attachment in people by virtue of their given social meanings. This awareness is reflected, for example, in the expectation that archaeological projects conducted in the U.S. include plans for consulting with the relevant descendent communities. Since the passage of the Native American Graves Protection and Repatriation Act in 1990, this ethic has been the norm for all archaeological projects funded or permitted by the United States government.<sup>12</sup>

However, biospecimens are unique in some respects: While we appreciate the potential scientific value of acquiring blanket consent for future uses of biospecimens, we wonder whether blanket consent forms could be administered ethically in medical contexts. Such forms are presented when persons are medical patients. They face signing all sorts of difficult-to-decipher forms at a time when they are concerned about their personal medical needs and are dependent on their doctors' and medical administrators' cooperation and attention. Under these conditions, they are highly unlikely to be in a position to reflect thoughtfully on requests for blanket consent. We strongly recommend that this problem be taken into account in any new rule wording regarding biospecimens.

<p style="text-align: center;"><b>V. Strengthening Data Protections to Minimize Information Risks (76 FR 44524-27: Part V, Questions 54-64)</b></p>
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**We oppose in the strongest possible terms the imposition of HIPAA protocols concerning data security and confidentiality on non-biomedical research.** An alternative recommendation is presented at the end of our Part V commentary (pp. 21-22).

We agree with introductory assertions in the ANPRM that the “increasing use of genetic information, existing (i.e., stored) biospecimens, medical records, and administrative claims data in research has changed the nature of the risks and benefits of research participation”; the ANPRM goes on to assert that the “risks related to these types of research are not physical but informational” and need to be mitigated as such (76 FR 44513-14).

The distinction between “informational” risks and “physical” risks is pivotal to the logic of this ANPRM. In the proposed rulemaking, research posing “physical” risks would be reviewed by IRBs, as in the current regulations, while research posing “informational” risks would be classified as “Excused” (a revision of the “Exempt” designation) and truly excused from IRB review. This change is intended to lighten IRB workloads, enabling them to focus on higher risk

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<sup>12</sup> See, e.g., <http://www.gsa.gov/portal/content/101901>.

research while acknowledging that IRBs are not well designed to control for “informational” risks.

However, once Part II (A) of this ANPRM begins, specifically biomedical references (prominent on 76 FR 44513-14 cited above) become less prominent and it is asserted more generally that, for various reasons (44515-16), “[s]tandardized data protections, rather than IRB review, may be a more effective way to minimize informational risks.” Therefore, the ANPRM proposes “mandatory standards for data security and information protection whenever data are collected, generated, stored, or used” (44516), applying those mandatory standards to prospective data collections (but perhaps not to research using existing data collections: 44525), without specifying the kinds of data collections being referred to.

Finally, levels of protection would be indexed to levels of identifiability, “based on the standards of identifiability under the HIPAA Privacy Rule” (44516). The ANPRM acknowledges that the Common Rule concept of “human subjects research” and the Health Insurance Portability and Accountability Act’s standards “are not aligned” (44525). The proposed solution calls for “adopting the HIPAA standards for purposes of the Common Rule”. That is, the proposed rulemaking would incorporate HIPAA definitions and standards: particularly, those relating to “individually identifiable information”, “limited data sets”, and “de-identified information” (44524-27). This extended proposal to make the Common Rule over in HIPAA’s image comes on the heels of a lengthy acknowledgement of the serious limitations of HIPAA and other available information control systems, especially in light of rapidly changing modes of digital information processing (44524-25).<sup>13</sup>

The problem is that, insofar as this strategic proposal is guided by a desire for “uniformity” (44525), it ignores differences among fields of study even where those differences are relevant to ethically meaningful oversight. By opting for uniformity and maximum inclusiveness, both the Common Rule and this ANPRM lose clarity and meaningful applicability across the diversity (and progressive diversification) of research activities.

Scaling data security and information protection standards to “the level of identifiability of the data” (44525) may make sense when personal health data are reused for research purposes. But “research” and “data” are simply not general phenomena. Standards designed to secure health insurance data are a poor model for the ethical management of humanistic social studies, whose very reason for being is the documentation and understanding of local cultural knowledge, sociocultural and historical contexts, processes, and events, and the works and lives of individual persons. Applying systems designed to protect health data to these sorts of research makes no sense intellectually or ethically.

For example, as noted in our response to Q 47-53 above, some kinds of biomedical materials like “biospecimens” are not only or simply biomedical “information”; they are

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<sup>13</sup> And see e.g., Narayanan and Shmatikov (2010) Myths and Fallacies of ‘Personally Identifiable Information’. [http://www.cs.utexas.edu/~shmat/shmat\\_cacm10.pdf](http://www.cs.utexas.edu/~shmat/shmat_cacm10.pdf).

simultaneously also socially-significant symbols of “personhood” for many people and communities (see also our response to Q 7). Consequently, they cannot be treated solely or simply as “personally identifiable information” such that it would be equally appropriate to approve (or waive) generalized consent documents or impose “standardized data protections” with respect to the secondary uses of blood samples and of social security numbers. (See also our response to Q 44 and Q 45 concerning the inapplicability to historical and anthropological research of biomedical ways of thinking about secondary uses of data not originally collected for research purposes.)

We have already explained how the definition of “research” encourages the inappropriate conflation of biomedical interventions and experimental methods with other kinds of study activities (e.g., Q 10, Q25). The definition of “human subject”, which also delimits the Common Rule’s applicable domain, similarly encourages biomedically-oriented uniformity in developing ethical oversight. The definition of “human subject” makes quite explicit reference to biomedicine (“venipuncture” and “medical records”). Indeed, the term is drawn from biomedical and experimental science usage, where “subjects” are understood to respond to stimuli introduced and controlled by experimenters. However, most social and humanities research construes human participants as more proactively engaged (in various particular senses) in the research process: as open-ended interview “respondents”, oral history “narrators”, or ethnographic “informants”, “consultants”, and “interlocutors”. Consequently, “human subject” imports misleading connotations into IRB evaluations of social and humanistic research (introducing inaccurate study design expectations concerning “subject selection” and the like). This consideration is directly relevant to our response to Q 59 below.

Recommendation #1 (pp. 3-4) aims to make the relevant distinctions. Building on the biomedical science references explicit throughout the present Common Rule and this ANPRM (though backgrounded in the key definitions), it makes the case for narrow but principled clarity.

While Recommendation #1 is a step toward correcting these definitional problems, it does not address the key innovation around which this ANPRM is organized: that is, the removal of work posing “informational” risks from IRB oversight and creation of an alternative method of ensuring ethical practice (the HIPAA model). Recommendation #2 below, while not a quick fix, offers an alternative to grafting HIPAA onto the Common Rule.

### **Recommendation #2**

From the 1970s onward, a key criticism of 45 CFR 46 has been that social scientists were never fully included in the crafting of these regulations, despite being immediately subject to them. Nowadays, as the ANPRM notes, IRBs find themselves reviewing an even more diverse world of research, one that has expanded to encompass sociocultural and humanistic fields even more distant from the “biomedical and behavior science” model on which the Common Rule is based. Imposing new guidance modeled on HIPAA—a set of standards that is intimately

tied to biomedicine—would simply repeat this original mistake, which has been a persistent source of alienation and resistance on the part of social and humanities researchers.

Indeed, the need for ethical review to be “multidisciplinary and pluralist” is recognized in the Universal Declaration on Bioethics and Human Rights (Article 19) as critical for assessing “the relevant ethical, legal, scientific and social issues related to research projects involving human beings”.<sup>14</sup> Therefore:

**We advocate the creation of a commission constituted specifically of social scientists (e.g., sociologists and the like), humanistic social researchers (e.g., cultural anthropologists and the like), and humanists (e.g., historians, legal scholars, and the like). Rather than adapting strategies developed to protect biomedical information—which are fundamentally incompatible with core intellectual and ethical commitments of humanistic social studies—this commission would be tasked with developing alternative guidance appropriate for their fields.**

Resources for the development of alternatives to the biomedical science model of research ethics abound. For example, over the past decade or so, the Interagency Advisory Panel on Research Ethics—which was set up by the Canadian Tri-Council (funding agencies representing health sciences, the natural sciences and engineering, and the social sciences and humanities)<sup>15</sup>—has worked to develop and update a research ethics policy that takes seriously the full diversity of knowledge-making practices.<sup>16</sup> In the U.S., contact with organizations such as the Association for Practical and Professional Ethics<sup>17</sup> would provide an excellent means for accessing the relevant expertise in social and humanistic research ethics. Professional associations such as the American Anthropological Association and those belonging to the Consortium of Social Science Organizations ought also to be enlisted in the drafting of appropriate regulatory guidance.

Meanwhile, colleges, universities, and other institutions should be encouraged to set up separate IRBs comprised of representatives of these fields (with the usual complement of community representatives), specifically empowered to develop locally appropriate modifications of the regulations, current and proposed.

#### Q 54

The use of HIPAA standards—“which were designed for dealing with health information”—are most definitely not “appropriate for use in all types of research studies, including social and behavioral research”. Our alternative proposal is outlined in Recommendation #2 above.

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<sup>14</sup> See the Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)

<http://unesdoc.unesco.org/images/0014/00146180e.pdf>.

<sup>15</sup> See <http://www.pre.ethics.gc.ca/eng/index/>.

<sup>16</sup> See especially: Panel on Research Ethics 2004 Giving Voice to the Spectrum. Report of the Social Sciences and Humanities Research Ethics Special Working Committee to the Interagency Advisory Panel on Research Ethics. Ottawa: Interagency Advisory Panel and Secretariat on Research Ethics.

<sup>17</sup> See <http://www.indiana.edu/~appe/>.

**Q 59**

Standards appropriate for the management of health information are most definitely not “appropriate...for all types of studies, including social and behavioral research”. Recent research by statisticians and information technology experts question whether HIPAA rules are adequate to protect study subjects from informational risks even in biomedical contexts (see, e.g., footnote 13).

This question also asks whether employing “different standards for different types of research” would make for “a better system”. Most definitely yes. Throughout this commentary, we have emphasized the need to make distinctions between, on one hand, biomedical and experimental behavioral science research and, on the other hand, humanistic social research. A “better system” would need to go way, way beyond the limp suggestion to “allow subjects to authorize researchers to disclose the subjects’ identities”. Allow? That suggestion demonstrates how utterly eclipsed the ethical principle of “respect for persons” has become by regulatory thinking about research ethics. For anthropologists of all kinds, this penumbra of participant disempowerment is disheartening, and most especially so given that this ANPRM is specifically intended to address Subpart A of the Common Rule, the part concerning “competent adults”.

**Q 66**

We strongly support empowering institutions with the “flexibility to determine” the structure of their own oversight responsibility, no matter what system is adopted. We attribute the phenomenon of “mission creep” in some part to the fact that institutions labor under the anxiety of federal audits. This contributes to an adversarial atmosphere in which it is only rational for boards and IRB administrators to emphasize bureaucratic documentation over situationally appropriate ethical decision-making.

**VI. Data Collection to Enhance System Oversight (76 FR 44527-28: Part VI, Questions 67-70)**

Questions 67-70 concern the reporting of information to federal authorities in such a way as to “allow for more powerful and meaningful analyses of safety information across types of research studies.” We are neutral on this matter in general. However, we do NOT believe that it is possible to create a uniform reporting mechanism that would be adequate to “all types of human subject research, including behavioral and social science research.” Even information as apparently straightforward as “number of research participants” requires nontrivial adjustment as one moves away from experimental contexts and toward more humanistic, interpretive methodologies such as participant observation.

**VII. Extension of Federal Regulations (76 FR 44528: Part VII, Question 71)**

This set of rule changes addresses the criticism that the present regulations do not cover “all” human subjects research. Presently, IRB review is required only for Federally funded projects, or for research conducted at institutions that accept Federal funding and that voluntarily “checked the box” on their FWAs. The ANPRM (76 FR 44528) considers the

possibility of extending “Common Rule protections to all research with human subjects conducted in the US regardless of funding source”, effectively withdrawing the freedom institutions currently have of developing alternative, locally appropriate mechanisms for ethical oversight of non-federally-funded research.

This move is unappealing on several grounds. It could greatly increase the quantity of reviews that IRBs need to handle, while failing to address the obvious fact that it still will not cover “all” human subjects research (e.g., witting or unwitting human participants in market research and the like are entirely unprotected by both the present and proposed regulations).

But the main problem we see with this set of suggestions is what it means for the rights of citizens in a free society, researchers and participants alike. The proposed changes would require the “registration” and “audit” of all study activities involving human beings regardless of funding source. How would such a system be delimited? Distinguishing necessary “regulation” from undemocratic “censorship” is a conundrum that needs to be faced.<sup>18</sup> Our Recommendation #1 aims to address the problem, however partially, by working to define the regulatory focus of 45 CFR 46 tightly and substantively, bearing clearly in mind the kinds of human research abuses the oversight system is intended to prevent.

#### **Q 71**

We strongly support staying with the present rule and FWA options, rather than extending the applicability of the Common Rule to all research regardless of funding source conducted at institutions that accept Federal funds.

<p><b>VIII. Clarifying and Harmonizing Regulatory Requirements and Agency Guidance (76 FR 44528-29: Part VIII, Questions 72-74)</b></p>
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We are neutral on this issue except for the following comment:

#### **Q 74**

This question asks whether “one set of guidance” would “be able to adequately address human subjects protections in diverse populations and contexts, and across the broad range of research contexts (including biomedical, national security, education and other types of social and behavioral research)”. As should be clear by this point, our answer is emphatically NO. The historical tendency to apply the Common Rule as if “research” were a uniform activity disregards the enormous conceptual, methodological, and ethical differences among different types of research. See Recommendation #2 above for our proposal to address this problem.

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<sup>18</sup> See, e.g., Hamburger (2007) “Getting Permission,” *Northwestern University Law Review* 101(2): 405-492 and Hamburger (2005) “The New Censorship: Institutional Review Boards,” *Supreme Court Rev.* 2004: 271-354; see also, e.g., contributions to *Law & Society Review* 41(4): 757-818 (2007): Feeley “Legality, Social Research, and the Challenge of Institutional Review Boards” plus commentaries and response.