Handout accompanying "**Impacts on Ethnographic Fieldwork of the 2011 Proposed Revisions to the Common Rule: With Special Attention to the 'Excused' Category**", a talk presented at the NRC workshop, *Revisions to the Common Rule in Relation to Behavioral and Social Sciences* (March 21-22, 2013, Washington, DC) by **Rena Lederman** (Professor of Anthropology, Princeton University)

Meaningful Limits on the Purview of IRBs

The following recommendations concerning the proposed revisions to human-subjects research protection regulations (an ANPRM and request for public comment published on July 26, 2011 in the Federal Register and available at http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf) *are adapted from the American Anthropological Association public commentary*.[1]

We made two basic recommendations, the first in the context of the ANPRM's Part II ("Ensuring Risk-based Protections") and the second in the context of the ANPRM's Part V ("Strengthening Data Protections to Minimize Information Risks"):

> **1.** To more narrowly delimit the object of Common Rule regulation (Recommendation #1 below).
>
> **2.** To set aside HIPAA as a framework for mitigating "informational" risks and convene a National Commission of social scientists and humanities scholars tasked with developing a framework for the promotion of ethical research conduct appropriate to non-biomedical, "informational risk" research (Recommendation #2, below pp. 3-4).

Recommendation #1

The vagueness of the key regulatory definitions is a fundamental 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 that construe an indefinite, globally inclusive concept of "research" 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 below addresses this fundamental problem by reversing the current strategy for deciding how activities are deemed within or outside the purview of the Common Rule and therefore of IRBs. The current strategy defines the object of regulation quite generally and then labors to identify and enumerate specific methodologies or types of study eligible for "exemption" or "expediting": experience (as reflected, for example, in the public commentary on Regulations.gov) has shown that this opt-out reviewing strategy engenders endless qualification and argument. In contrast, our Recommendation #1 defines the regulatory object specifically and then presumes all unnamed activities to be exemptible 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

[1] I was a co-author of the AAA commentary -- the original full text is available at http://www.aaanet.org/issues/policy-advocacy/Protecting-Human-Subjects.cfm -- and can be contacted at lederman@princeton.edu.

move grounds the IRB decision model on the ethical rationale that originally prompted human research ethics regulations and that remains salient today.

We 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 <u>study procedures involving risks of physical harm to human participants</u>: 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 <u>methodologies whose results depend for their validity on controlling the information available to research subjects</u>: that is, study designs reliant either on the passive withholding of information concerning the study activities, or on the active provision of misinformation about those activities (e.g., the use of placebos in biomedical clinical trials, or of confederates in behavioral research).**

Human experimentation involving systematic withholding of information and, particularly, instances of biomedical research that caused physical harm were central to the rationale that originally prompted the promulgation of 45 CFR 46 and establishment of IRBs.

The proposed "registration" procedure (outlined in FR 44515 (4)(i)) would thus ask PIs whether their planned work includes (1) biomedical and other 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 necessary element of study design. The decision-making process necessary to distinguish "minimal" from "greater than minimal" risk and "expeditable" from "full board" review (a focus of FR 44514-21: Part II)) would thereby pertain to two well-defined types of studies qualifying for IRB evaluation.

Meanwhile, lists of exemptible categories would no longer need to be exhaustively enumerated (as in 45 CFR 46.101(b) and associated ANPRM public commentaries) and updated. Posing neither potential "physical" risks nor the "psychological" risks associated with deception, they would all (in ANPRM terms) be "registered" and "excused" from IRB review, but subject to appropriate protections for "informational" risks (e.g., breaches of confidentiality). As to those appropriate protections, see Recommendation #2 below.

Recommendation #2

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 continue to be reviewed by IRBs, while research posing "informational" risks would be "registered" and then "excused" from IRB review. This innovation is the key way in which the ANPRM lightens IRB workloads, enabling them to focus on higher risk research.

However, the innovation hinges on a proposed "new mechanism for protecting subjects from informational risks" (Part II (A), 76 FR 44515-16). This new mechanism would be modeled on HIPAA standards: an idea introduced in Part II of the ANPRM and spelled out in more detail in Part V (FR 44524-27). Following HIPAA, mandatory standards for data security and information protection would be applied to prospective data collections of all kinds (not just the health records for which HIPAA was designed). Levels of protection would be indexed to levels of identifiability, based on standards set under the HIPAA "Privacy Rule" (FR 44516).

Now, 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" (FR 44525). Nevertheless, the proposed rulemaking would incorporate HIPAA definitions and standards: particularly, those relating to "individually identifiable information", "limited data sets", and "de-identified information" (FR 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 (FR 44524-25).[2]

Insofar as this proposal is guided by the bureaucratic ethic of "uniformity" (FR 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" (FR 44525) may make sense when personal health data are reused for research purposes. But "research" and "data" are simply not generic phenomena. Standards designed to secure health insurance data are an exceedingly 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.

While Recommendation #1 is a step toward correcting the fundamental definitional problems underlying the relentless expansion of IRB regulatory control, it does not address the key innovation around which this ANPRM is organized: that is, the removal of research posing "informational" risks from IRB oversight and adoption of the HIPAA model as an alternative

[2] See, for example, Narayanan and Shmatikov (2010) Myths and Fallacies of 'Personally Identifiable Information'. http://www.cs.utexas.edu/~shmat/shmat_cacm10.pdf

method for mitigating those risks. Recommendation #2 below, while not a quick fix, offers an alternative to grafting HIPAA onto the Common Rule.

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 encompassing sociocultural and humanistic fields even more distant from the "biomedical and behavior science" model to which the Common Rule repeatedly refers. Imposing new guidance modeled on HIPAA—a set of standards that is intimately tied to biomedical risks—would simply repeat this 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 Article 19 of the 2005 Universal Declaration on Bioethics and Human Rights as critical for assessing "the relevant ethical, legal, scientific and social issues related to research projects involving human beings" (http://unesdoc.unesco.org/images/0014/00146180e.pdf).

We therefore recommend the creation of a National Commission constituted specifically of social scientists (e.g., sociologists), humanistic social researchers (e.g., cultural anthropologists), and humanists (e.g., historians). 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 and an institutional framework appropriate for non-biomedical ("informational" in ANPRM terms) research risks.

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 (http://www.pre.ethics.gc.ca/eng/index/)—set up by the Canadian Tri-Council (funding agencies representing health sciences, the natural sciences and engineering, and the social sciences and humanities)—has worked to develop and update a research ethics policy that takes seriously the full diversity of knowledge-making practices.[3] Likewise, in the U.S. organizations such as the Association for Practical and Professional Ethics (http://www.indiana.edu/~appe/) could be tapped as sources of relevant expertise in social and humanistic research ethics. Professional associations such as the American Anthropological Association and American Historical Association ought also to be enlisted in the drafting of appropriate regulatory guidance, the creation of a case study repository, and related support.

In the interim, 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 modifications of the regulations, current and proposed, designed for non-biomedical, "informational" risk research.

[3] 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.