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1 January 2016

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections (OHRP)
Department of Health and Human Services

Dear Dr. Menikoff:

Thank you for the opportunity to comment on the September 8 notice of proposed rulemaking: Federal Policy for the Protection of Human Subjects, docket ID number HHS-OPHS-2015-0008.

I write these comments as the author of “How Talking Became Human Subjects Research: The Federal Regulation of the Social Sciences, 1965–1991,” *Journal of Policy History* 21 (2009): 3-37, and *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965–2009* (Baltimore: Johns Hopkins University Press, 2010), and as the editor of the Institutional Review Blog, <http://www.institutionalreviewblog.com>, all of which were graciously cited in the NPRM.

Most recently, in November 2015, I participated as a panelist in the Chicago round of the workshops on “Revising and Expanding the Scope of the Common Rule,” sponsored by the CTSA Consortium Coordinating Center (C4). I also offered assistance to the drafters of the comments on the NPRM submitted by the National Coalition for History, and I endorse those comments.

In addition, I wish to offer the following observations, which reflect only my views and may not represent those of historians’ organizations, George Mason University, or any other institution.

Sincerely,

A handwritten signature in black ink, appearing to read "Zachary Schrag". The signature is fluid and cursive.

Zachary Schrag
Professor of History

Title and letterhead are used for contact information and identification only. These views may not reflect those of George Mason University.

**Zachary M. Schrag. Comments on Notice of Proposed Rulemaking:
Federal Policy for the Protection of Human Subjects. 1 January 2016**

The proposed rule is designed “to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.” So far as research in the social sciences and humanities is concerned, several of its provisions are likely to achieve these goals, so I applaud this effort and look forward to the final rule. However, I wish to draw attention to some of the limits of the proposals, particularly in the areas of due process protections, empirical research, and revision in light of experience.

The Common Rule should adhere to statutory law

- **HHS and other regulatory agencies lack the authority to regulate research in the humanities and social sciences**

The NPRM cites as its statutory authority 42 U.S.C. 289, which applies to “biomedical or behavioral research involving human subjects,” and does not mention social science or research in the humanities. As the NPRM acknowledges, “some of the commenters [on the ANPRM] recommended that the definition of research be focused more explicitly by being limited to ‘biomedical and behavioral research,’ in accordance with the statutory provision underlying the Common Rule.” But it makes no effort to focus the definition or to explain why the drafters felt comfortable ignoring this part of the statute.

The Common Rule should be restricted to biomedical or behavioral research involving human subjects as provided for by the statute.

- **HHS lacks statutory authority to regulate research not directly funded by the Public Health Service**

42 U.S.C. 289 requires IRB review of research supported by a “grant, contract, or cooperative agreement under this chapter.” When the 1981 version of 45 CFR 46 was promulgated, the Federal Register notice explained,

HHS has carefully considered its proposed policy regarding the regulation of non HHS-funded research in light of the comments received and the statutory basis for the more expansive interpretation. The public comment, including that of the President’s Commission, revealed a broad based and significant amount of objection to the extension. Further, the HHS General Counsel has advised that there is no clear statutory mandate in the National Research Act to support a requirement for IRB review of other than Public Health Service-funded research. Therefore, the Secretary of HHS, after considering a number of possible options, has decided not to extend the requirements for prior IRB review and approval to non HHS-funded research. (46 FR 8369)

In 1996, OPRR director Gary Ellis repeated this finding, telling the National Bioethics Advisory Commission, “It is not clear where the authority would come from to requiring

institutions that receive money for this project to apply the rule to that project.” (National Bioethics Advisory Commission, transcript, inaugural meeting, 4 October 1996, p. 211, <http://bioethics.georgetown.edu/nbac/transcripts/1996/10-4-96.pdf>.)

The NPRM “proposes an extension that would ensure that clinical trials are covered by the Common Rule if conducted at an institution in the United States that receives federal support for non-exempt and non-excluded human subjects research, regardless of the funding source of the specific clinical trial.” It acknowledges that ANPRM comments “argued that such a change was an overreach of federal oversight and constituted an unfunded mandate.” But it offers no legal analysis of why regulators have rejected public concern and the legal reasoning of previous HHS counsel.

If HHS wishes to regulate clinical trials regardless of the funding source of the specific clinical trial, it should suggest that change to Congress. Under current law, HHS has no authority to impose this regulation.

The proposals for interview research are helpful but incomplete

- **Oral history, journalism, biography, and historical scholarship should be excluded**

The proposed rule would “explicitly exclude oral history, journalism, biography, and historical scholarship.” This is a welcome change and addresses the concerns put forth by historians and journalists since the first imposition of IRB review on their work in the 1990s. I endorse the comments provided by the National Coalition for History:

We concur with this recommendation of full exclusion of such activities from IRB oversight. It reflects an appreciation that these activities should not be evaluated under frameworks originally designed with the sciences in mind. It recognizes the value and attributes of these forms of scholarship. It eliminates any ambiguity about review, regulation and enforcement, and thus removes an enormous and contentious burden for both scholars and IRBs.

- **Oral history, journalism, biography, and historical scholarship should not be subject to the Belmont Report**

The NPRM states that “All investigators performing excluded studies are expected to act in a way that is consistent with the principles outlined in the Belmont Report, even if the Common Rule does not impose requirements on excluded work.” This is inconsistent with the NPRM’s acknowledgment that “these fields of research have their own codes of ethics.” Historians, journalists, and biographers write critically about the people they study. Since the Belmont Report does not address such critical inquiry, it is a poor guide for their work.

- **Other on-the-record interviews should be excluded**

Scholars in law, political science, folklore, and other fields also frequently “focus directly on the specific individuals” they study, and conduct interviews, correspondence, or other

forms of interaction with these individuals. OHRP itself conducts such studies when it solicits public input on its proposals; all comments on the NPRM provide information about individuals obtained through interaction, yet they are not nor should be subject to IRB review.

When interviews and other interactions are on the record, with the expectation that participants' real names will be used in any resulting study, the federal government has no business regulating the exchange of information and ideas between consenting adults.

In its NPRM comments, the Secretary's Advisory Committee on Human Research Protections suggests modifying this provision to exclude "Oral history, journalism, biography, historical, and other scholarship activities whose purpose is to collect and share evidence-based portrayals of specific individuals who have been selected as a result of the relevance of their personal experience to the phenomena being studied." This is not quite right, since, as Charles Seife points out in his comments, history and journalism interviews do not merely collect portrayals of the people being interviewed, but also other information known to specific individuals.

A better exclusion would be for :

"Oral history, journalism, biography, historical, and other scholarship activities whose purpose is to collect and share information from specific individuals who have been selected as a result of the relevance of their personal experience to the phenomena being studied."

- **Rules on ethnography must be clarified**

Neither the NPRM nor the proposed rule uses the term "ethnography," and it is unclear how the rule would affect that practice.

At the October 20 Public Town Hall Meeting, Julia Gorey responded to a written question from Edward Liebow of the American Anthropological Association by suggesting that a great deal of ethnography could be excluded under section 101.b.2.i. or exempt under 104.e.1. Yet this is presumably further qualified by the proposed § ____ .101(b)(2), which limits the exclusion's application to subpart D, i.e., research with children. And SACHRP's recommendations, if followed, would further muddy the picture by making some of this work "exempt" rather than excluded.

Ethnographers deserve more clarity. If provisions for ethnography are to be split among multiple parts of the rule, with further cross-references to Subpart D, OHRP should work with the American Anthropological Association, the American Sociological Association, and other scholarly organizations to craft a guidance document specifically for ethnographic research.

- **Low-risk conversations should be excluded, not exempt**

PRIM&R and SACHRP have opposed the proposed exclusion of "Research, not including interventions, that involves the use of educational tests (cognitive, diagnostic,

aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) uninfluenced by the investigators” (§.101(b)(2)(i)). These forms of research should remain in the excluded category.

For twenty years, IRBs and IRB offices have interfered with exempt research, to the extent that “exempt” no longer means exempt, but rather has become a “type of IRB review.” (University of Southern California OPRS Office for the Protection of Research Subjects, “Types of IRB Review,” <http://oprs.usc.edu/review/typesofirb/>.) If the low-risk methods identified in (§.101(b)(2)(i)) are moved to the exempt category, scholars in the social sciences and humanities will continue to face undue burden, delay, and ambiguity, while IRBs and their staff will continue to be distracted by low-risk proposals to the detriment of attention to truly risky projects.

The Common Rule should increase the transparency of the review process

The NPRM proposes “public posting of consent forms ... to increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the development of future consent forms.” This is a step in the right direction, but it is too limited.

Rather than posting only final consent forms, the federal site should allow researchers to post their proposed consent forms, so that the public could see the kinds of changes demanded by IRBs.

Better still would be the collection and posting of proposals and IRB decisions. As Jay Katz testified in 1973,

The review committees work in isolation from one another, and no mechanisms have been established for disseminating whatever knowledge is gained from their individual experiences. Thus, each committee is condemned to repeat the process of finding its own answers. This is not only an overwhelming, unnecessary and unproductive assignment, but also one which most review committees are neither prepared nor willing to assume. [U.S. Senate, *Quality of Health Care—Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, Part 3* (93d Cong., 1st sess., 1973), 1050].

This is as true today as it was in 1973, despite repeated calls for IRBs to base their decisions on evidence and precedent, and a small pilot project by the University of Otago. (See Alexander Halavais, “Social Science: Open Up Online Research,” *Nature* 480 (8 December 2011): 174–175, doi:10.1038/480174a; Robert Klitzman, “Who Polices the ‘Ethics Police’?,” CNN, May 26, 2015; Tolich, Martin, and Emma Tumilty. “Making Ethics Review a Learning Institution: The Ethics Application Repository Proof of Concept. Tear.otago.ac.nz.” *Qualitative Research* (January 3, 2013). doi:10.1177/1468794112468476.)

The revision of the Common Rule offers an opportunity to increase transparency, enhance confidence in the research enterprise, and increase accountability by

disseminating knowledge in the form proposed by Katz. This should not be limited to finalized consent forms.

The Common Rule should require appeal mechanisms

The 2011 ANPRM proposed “a requirement that every institution must provide an appropriate appeal mechanism.” Such a provision could help provide transparency and accountability to the IRB process.

An appeals process is already included in Canada’s TCPS2 (articles 6.18 and 6.19), and it was recommended by the National Research Council’s 2014 report, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences* (Recommendation 6.3).

The NPRM fails even to mention appeals, dismissing the NRC recommendation without reason. The final rule should restore the requirement for an appeals mechanism.

Common Rule agencies should sponsor ongoing empirical research and use it future regulatory revision

Questions 27 - 32 asks the public to speculate on the prospect of an “automated exemption decision tool.”

This should be a matter of empirical knowledge, not mere speculation. In October 2009, OHRP stated that “an institution might craft a checklist for certain exemption categories, with questions that are easily answered ”yes“ or ”no“ by an investigator, with certain answers leading to a clear conclusion that the study is exempt... . A web-based form might be created that served the same purpose, allowing the researcher to begin the research immediately after submitting the required information using the web form. In both instances, the key issue would be whether these procedures lead to correct determinations that studies are exempt.” (https://web.archive.org/web/20091016101015/http://www.hhs.gov/ohrp/policy/exempt_res_det.html.) So we should have six years of data on the workings of these tools. We do not.

OHRP has failed to encourage institutions to experiment with such promising procedures or to fund studies about the effectiveness of various alternative systems. Rather than continuing to rely on guesswork, the Common Rule agencies should jointly sponsor empirical research to learn what does and does not work in ethics review. This concerns not only the exemption decision tool, but all manner of human subjects research oversight.

Explaining the ANPRM to the Presidential Commission for the Study of Bioethical Issues in August 2011, ANPRM architect Ezekiel Emanuel stressed his wish for a “risk-based review process” and “a learning process that would be constant and dynamic to reflect actual risk” rather than what he termed “gut reactions ... which is worthless.” Whether through a provision in the new rule or another mechanism, Common Rule agencies should institute such a learning process.

Common Rule agencies should provide prompt, clear guidance in response to questions about regulation

Question 73 asks, “Will the proposed language at §__.101(j) be effective in achieving greater harmonization of agency guidance, and if not, how should it be modified?”

HHS has failed its statutory responsibility to “establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.” (42 U.S.C. 289) While OHRP sporadically issues interpretations, these are few and insufficient. As Robert Klitzman has documented in his book, *The Ethics Police?*, when IRBs seek help from OHRP, officials there “essentially just read back the regulations” or offer “vague generalities.” (p. 185) The proposed language offers little hope for a remedy. Indeed, by demanding consultation among so many federal agencies, it threatens to slow an already deficient guidance system.

By contrast, Canada’s Panel on Research Ethics offers relatively prompt, clear guidance in response to the questions it receives (<http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/Default/>). Unlike SACHRP, whose members know only biomedical and psychological research, the panel is composed of “a wide spectrum of expertise and experience in the ethics of human research, such as research involving Aboriginal peoples, ethics and ethics review, research administration, research in the health, natural and social sciences, humanities and engineering, law, as well as a lay perspective.” (<http://www.pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/>)

The Common Rule agencies need to follow this model and establish an interagency panel, staffed with experts in all forms of regulated research, who can offer prompt, authoritative, precise guidance on matters of regulatory interpretation.

Common Rule agencies should continuously revise the Common Rule

The NPRM promises that the list of activities deemed minimal risk will be updated “at least every 8 years.” While that’s helpful, it also suggests that the NPRM framers do not expect that the rest of the regulations will be regularly revised, or at least not more frequently than once a generation.

That is a disappointment. Canada has shown the value of more frequent revision, with a wholesale revision after 12 years, and a significant update after only four. The United States should follow this model by collecting data on the workings of the new rule and suggesting revisions in roughly four-year cycles. As PRIM&R notes in its draft comments, attempting to overhaul the regulations in their entirety impedes careful consideration of each part. It would be healthier to address one issue at a time, and build a system of continuous revision in light of experience.