



January 6, 2016

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections (OHRP)
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: HHS–OPHS–2015–008 (Federal Policy for the Protection of Human Subjects)

Dear Dr. Menikoff,

On behalf of the Population Association of America (PAA) (www.populationassociation.org) and the Association of Population Centers (APC) (www.populationcenters.org), we are pleased to comment on the Notice of Proposed Rule Making (NPRM) revisions to the Common Rule (HHS-OPHS-2015-008).

PAA is the premier professional, scientific society for more than 3,000 behavioral and social scientists—including demographers, sociologists, economists, epidemiologists and statisticians—who study the implications of population change. Our members conduct research and train young scientists at U.S. universities and independent research organizations. The APC is composed of approximately 40 federally funded, interdisciplinary population research centers nationwide. Given the interdisciplinary nature of population research, our members are involved in many aspects of human subjects research, but, in particular, survey research. For this reason, our comments focus almost exclusively on the proposed regulations as they affect collecting, accessing, and protecting survey data related to the behavioral and social sciences in particular.

Overall, we are very pleased with the proposed revisions to the NPRM. We found the proposal responsive to the concerns our organizations raised in our October 26, 2011 letter, responding to the Advanced Notice of Proposed Rule Marking (ANPRM) concerning the “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators.” Further, we found the revisions responsive to the National Research Council Report¹ on the ANPRM from the perspective of the behavioral and social sciences.

- In particular, we are encouraged by the following provisions in the NPRM:

¹ National Research Council. (2014). *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences*. Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences. Board on Behavioral, Cognitive, and Sensory Sciences, Committee on National Statistics, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press.

- Relative to the past, the NPRM would either excuse or exempt many types of low-risk behavioral/social science research, such as that with minimal or no informational risk to subjects, where data are de-identified, and the research is being conducted using publicly-available information, etc....;
- In contrast to the ANPRM, the NPRM does not stipulate that HIPAA be required as the standard for data security and information protection;
- It *excludes* from human subjects activity, data collected in surveys if the data are collected without personally identifiable information OR minimal risk and *exempts* data collected from such surveys even if data are not de-identified and are subject to more than minimal risk so long as adequate privacy protections are followed;
- The NPRM reduces the burden to studies by stipulating that a single IRB should be the controlling entity for multi-site studies; the NPRM also provides useful clarification of what is and is not a multi-site study;
- It now requires the use of simplified consent statements, which is an important advance for data collection from human subjects by population scientists;
- It allows broad consent for future use of biospecimens and data;
- It strengthens and clarifies privacy and security safeguards;
- It streamlines IRB review procedures (e.g., no IRB approval required for minor changes in approved research); and,
- It streamlines IRB review procedures for materials and methods.

Despite our overall very positive reaction to the NPRM, we want to raise several concerns and issues that should be clarified in the final regulations and guidelines. These include the development of data safeguarding requirements, the implications of the “broad consent” provisions for data linkage, and the development of examples of minimal risk activities. Our concerns also touch on the template for “broad consent” that the Secretary of HHS will develop.

Data safeguarding requirements

Section 105 (b) indicates that “the Secretary of HHS shall establish a list of specific measures that... will be deemed to satisfy the requirements for reasonable and appropriate safeguards.” These will comprise one of several standards that investigators can adopt to meet requirements for safeguarding the confidentiality of data and privacy of research participants. The details of these data safeguarding measures are highly significant. They may provide important clarity and useful guidance, or they may be costly, burdensome, and ineffective. We urge that these standards: (a) reflect the input of experts in behavioral and social sciences research; (b) embrace a tiered approach tailoring safeguarding requirements to different “levels” of data sensitivity (e.g., requiring higher safeguarding standards for data that are more sensitive, such as information on illegal behaviors, sexual activity, and income and wealth); and (c) account for the risks of indirect identification of research subjects, such as through the combination of individually non-identifiable data on geographic, demographic, and socioeconomic characteristics (i.e., deductive or indirect disclosure risk).

Broad Consent Implications for Data Linkage

The final rule should clarify the implications of the “broad consent” provisions for data linkage of survey respondents to external data sources such as administrative records. Specifically, it is not apparent in the NPRM that new broad consent statements focused on future use of biospecimens also extend to future data linkage to external databases and data sources. We recommend that broad consent also cover unspecified data linkages in the final rule.

Minimal Risk Determination

The NPRM proposes no changes to the existing definition of minimal risk, and criteria for exemption given in Section 104 (d)(3)(i)(B), “Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation,” would maintain existing understandings of this concept within the social sciences. However, Section.102 (j) states that “the Secretary of HHS will maintain guidance that includes a list of activities considered to involve no more than minimal risk.” We suggest that input from social scientists employing diverse research designs be obtained in developing this list. In a similar vein, we also suggest that social scientists provide input in the development of the proposed web-based tool that HHS will develop for use by researchers to determine whether their study is exempt from human subjects research requirements and of the template for “broad consent” that the Secretary of HHS also will develop.

In closing, PAA and APC commend HHS and the Office for Human Research Protections for undertaking this ambitious, and long overdue, effort to modernize the fundamental law governing human subjects research. While we appreciate the numerous public comment opportunities, we want to encourage the Administration to get input from experts across all disciplines representing the behavioral and social sciences to address the complex issues the NPRM raises in next phases of its development and implementation.

Once again, thank you for giving the research community an opportunity to comment on the proposed changes, and we look forward to working with our federal partners on this ongoing, critical initiative.

Sincerely,



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President, Population Association of America



Lisa Berkman, Ph.D.
President, Association of Population Centers