



ASSOCIATION OF POPULATION CENTERS POPULATION ASSOCIATION OF AMERICA

*President of Association
of Population Centers*
James R. Walker, Ph.D.

*President of Population
Association of America*
David Lam, Ph.D.

*Director,
Government Affairs*
Mary Jo Hoeksema, M.P.A.

1701 K Street NW,
Suite 1150
Washington, D.C. 20006

(202) 341-7283 office
(202) 842-2788 fax
paaapc@crosslink.net

<http://www.popassoc.org>
<http://www.popcenters.org>

October 26, 2011

Jerry Menikoff, M.D., J.D.
Department of Health and Human Services
Office of Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Response to HHS-OPHS-2011-0005

Dear Dr. Menikoff,

On behalf of the Population Association of America (PAA) and Association of Population Centers (APC), we are pleased to provide the following comments on the advance notice of proposed rulemaking (ANPRM) entitled, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." PAA and APC endorsed a white paper submitted by Dr. Felice Levine, American Education Research Association, representing the views of several behavioral and social science research organizations. Our comments reflect priorities PAA and APC identified from the white paper and comments individual PAA and APC members have submitted formally and informally.

The PAA is a professional organization of over 3,000 individual members who conduct research on the implications of population change. PAA members include demographers, sociologists, economists, health scientists, and statisticians. The APC is an organization comprised of over 40 universities and research groups nationwide whose mission includes fostering collaborative demographic research and data sharing and translating basic population research for policy makers. 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 longitudinal survey data in particular.

As a general comment, our members are concerned about the degree to which the proposed regulations are derived from protections established by the Health Insurance Portability and Accountability Act (HIPAA). HIPAA as a privacy protection regulation for administrative records is a misfit for guiding research data protection and security plans. The revised regulations need to set a standard appropriate for the forms of data being collected and protected and devise a mechanism to delegate that certification for registered research, involving different levels of informational risk and forms of data, rather than applying HIPAA standards uniformly. We encourage the Department of Health and Human Services (HHS) to consider existing guidelines (e.g. Confidential Information Protection and Statistical Efficiency Act, NAS CNSTAT reports, etc...) for developing a new common standard. PAA and APC endorse an idea forwarded by other groups, suggesting an independently commissioned National Research Council study to review the proposed regulations

and inform issues under consideration (including data access and confidentiality protection, the consent process, and exempt versus excused research project categories) and other issues that have not been systematically examined since the establishment of the Common Rule.

Informed Consent

Given the prominence that longitudinal, large-scale federal surveys play in the population sciences, PAA and APC members are concerned about the potential effect the proposed regulations could have on existing surveys—especially as the regulations pertain to informed consent. To many of our members, it is not clear that data and biospecimens collected as part of ongoing longitudinal panel studies would be covered, given that some of the data would be collected after the effective date of the new rules. We urge the Department to consider applying new protections only to prospective collections of data and biospecimens after the implementation of any changes to the Common Rule and not retrospectively to research involving existing data, including stored biospecimens and their subsequent analysis. Even for future research, however, it is not always feasible to require participants in large surveys to be re-contacted for consent every time their data are used in secondary data analysis. Large surveys collected for public use, such as the Panel Study of Income Dynamics, Health and Retirement Study, and the National Survey of Family Growth, are designed to cover a very broad range of research questions. The final regulations should reflect this unique aspect of large, public surveys.

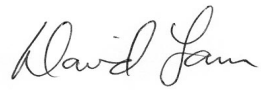
Multi-Site Review

PAA and APC support the proposed change, allowing for the use of one Institutional Review Board (IRB) of record for multi-site studies. As the proposed regulations are clarified, however, we encourage HHS to clarify the term “multi-site.” A single investigator or institution may conduct a study with data collection or other human subject interventions at multiple sites. To avoid confusion we suggest that the rules distinguish on the basis of researcher affiliation between single institution, multi-site research, and multi-institution research whether at a single site or many. If both situations are to be covered this should be clearly stated.

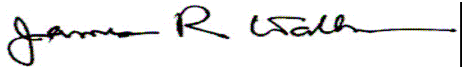
As a general comment, we want to underscore that most behavioral and social science research is “low risk” research. While physical risks generally are the greatest concern in biomedical research, social and behavioral studies rarely pose physical risk, but may pose psychological or informational risks. Some have argued that, particularly given the paucity of information suggesting significant risks to subjects in certain types of survey and interview-based research, the current system over-regulates such research. Further, many critics see little evidence that most IRB review of social and behavioral research effectively does much to protect research subjects from psychological or informational risks. Over-regulating social and behavioral research in general may serve to distract attention from attempts to identify those social and behavioral research studies that do pose threats to the welfare of subjects and thus do merit significant oversight. The proposed regulations are an opportunity to re-focus IRBs on what constitutes high-risk research across all disciplines.

In closing, PAA and APC commend HHS and the Office of Science and Technology Policy for undertaking this ambitious, and long overdue, effort to modernize the fundamental law governing human subjects research. We 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,

A handwritten signature in cursive script that reads "David Lam".

David Lam, President
Population Association of America

A handwritten signature in cursive script that reads "James R. Walker", followed by a vertical line.

James R. Walker, President
Association of Population Centers