December 21, 2007

Expedited Review
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Comments on Proposed Revisions to the Expedited Review Categories of Research

To the Office of Human Research Protections:

Thank you for the opportunity to comment on the proposed changes to the expedited review categories of the federal human research protection regulations (45CFR46). Representatives of a large number of professional societies in the social and behavioral sciences discussed the proposed changes as described in the Federal Notice dated October 26, 2007. We believe that the proposed changes overall are quite useful. Nevertheless, we wish to make some recommendations about the implementation of these changes and also offer some modest modifications that we believe will strengthen and clarify your intent as well as avert any misinterpretation.

Before setting forth our specific recommendations, we wish to situate our comments in the context of larger issues raised by the proposed changes. Despite considerable discussion over the last five or more years,¹ we remain concerned about the absence of sufficient understanding on the part of Institutional Review Boards (IRBs) about the breadth of minimal risk research in the social and behavioral sciences (SBS), the need for 45CFR46 to be more judiciously applied, and the range of SBS research that should be exempt from review or is appropriate for expedited review even under the current categories. The absence of any visible net improvements in advancing the sound review of social and behavioral sciences research has impeded some important research, limited training opportunities, and unfortunately produced disaffection on the part of too many researchers, while also distracting IRBs from matters needing their time and attention.

¹ In 2003, the National Research Council (NRC) Panel on Institutional Review Boards, Surveys, and Social Science Research provided an excellent analysis of the current situation and gave constructive recommendations on minimal risk research and exempt and expedited review in Protecting Participants and Facilitating Social and Behavioral Sciences Research (see especially chapter 4). In 2004, the Social and Behavioral Sciences Working Group specifically advanced a working paper to OHRP on Institutional Arrangements for Reviewing Exempt, Expedited, or Other Research and Research-Related Activities. While this report was directed to institutions so that they could operate more effectively, without acknowledgement of the value of doing so from OHRP, institutions are not likely to modify their practices. (The SBS Working Group was originally established by the National Human Research Protections Advisory Committee [NHRPAC] and subsequently continued with contractual support from the National Institutes of Health Office of Behavioral and Social Sciences Research.)
Given this long-term situation, it would be extremely helpful if OHRP, in issuing these changes to the expedited review categories, could take the opportunity to emphasize the importance of implementing these changes consonant with the intent of the exempt and expedited sections of 45CFR46. Also, in any transmittal sent to institutions, it would be useful to include language specifically directed to the consideration of social and behavioral science protocols, perhaps encouraging attention to other relevant recommendations from NHRPAC, the Secretary's Advisory Committee on Human Research Protections (SACHRP), as well as to the NRC and Working Group reports (cited in footnote 1 above). In addition, we strongly urge OHRP to consider collecting information on IRB’s (such as through a routine reporting or audit procedure) in order to provide a better sense of their performance and allow for the sharing of best practices. To date, little is known about IRB operations, and yet the primary oversight responsibility lies with these local boards.

Specific recommendations regarding the language of Categories 5 and 7 are shown below.

**Category 5**

As indicated in the Federal Notice, OHRP proposes to change the wording of Category 5 “to clarify that the category includes research involving materials that were previously collected for either nonresearch or research [emphasis added] purposes, provided that any materials collected for research were not collected for the currently proposed research.” We agree with the proposed language for the category, but also recommend changes to the “Note” to emphasize that expedited review is only applicable when the research is not exempt.

Our recommendation for Category 5 is as follows:

(5) Research involving materials (data, documents, records, or specimens) that

(a) have previously been collected for nonresearch purposes;
(b) have previously been collected for research purposes, provided the materials were not collected for the currently proposed research; or
(c) will be collected solely for nonresearch purposes.

Note: This listing refers only to research that is not exempt. Some research under section (a) or (b) of this category is exempt from the HHS regulations for the protection of human subjects. As stated in 45 CFR 46.101(b)(4), research activities are exempt from the federal policy if the only involvement of human subjects pertains to “research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in
such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.”

[Highlighted area indicates an addition or change to OHRP’s recommendation.]

**Category 7**

According to background materials, the Secretary’s Advisory Committee on Human Research Protections recommended changes to Expedited Review Category 7. The recommendation was made in a letter to the Department of Health and Human Services Secretary dated March 14, 2007, but no further details on the proposed change were provided. The social and behavioral science societies listed below agree in general with the proposed changes to the category, but recommend adding the language “experimental or non-experimental” to clarify that research using the experimental method may also qualify for expedited review if the procedures are otherwise deemed to be of minimal risk. As with Category 5, we also recommend language changes to the accompanying “Note” to signal that the exemption which may apply is not limited to the (b)(2) and (b)(3) categories. Specifically, we recommend the following language for Category 7:

Research (a) on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, affective states, interpersonal relationships, identity, language, communication, cultural beliefs or practices, and social behavior); or (b) employing experimental or non-experimental methods commonly used in social, behavioral, epidemiologic, health services and educational research (including, but not limited to, survey, interview, oral history, participant observation, ethnographic, focus group, program evaluation, human factors evaluation, or quality assurance methods).

Note: This listing refers only to research that is not exempt. Some research in this category is exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b).

[Highlighted area indicates an addition or change to OHRP’s recommendation.]

In addition to these specific recommendations directed to the proposed change, we also want to underscore the importance of an expedited review process—that is, a timely and efficient process for protocols that are minimal risk and do not require a full review. We note the recommendation by SACHRP directed to OHRP and the FDA to modify the regulations and replace the term “expedited review” with the term “delegated review.” While we understand that the term delegated review may more accurately describe the
process, if such a change is made, we encourage explicit mention that review is “delegated” in order to expedite the process.

We appreciate the opportunity to comment on the categories and commend OHRP for moving forward with changes that, with appropriate guidance, may help to improve the operation of the human research protection system. We also urge OHRP to use its good offices to situate these changes in the larger context that necessitates these clarifications.

Sincerely,

American Educational Research Association
American Political Science Association
American Psychological Association
American Sociological Association
Association for Psychological Science
Association for Public Policy Analysis and Management
Association of Population Centers
Consortium of Social Science Associations
Law and Society Association
Population Association of America
Society for Research in Child Development