



Date: February 12, 2013

To: Office of Management and Budget

Through: Mikia Currie, NIH Project Clearance Officer

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Subject: Revision of the Information Collection Request for Wave 2 of the *Healthy Communities Study: How Communities Shape Children's Health*

The Healthy Communities Study (HCS) is submitting an Information Collection Request (ICR) revision under the Paperwork Reduction Act. This request is for Wave 2 of the HCS. We respectfully note that this ICR submission is time sensitive if the HCS is to successfully complete the study as planned. As described further below, Wave 2 family participants are to be recruited through elementary and middle schools; in order to meet the timeline, and complete all currently planned study activities within the HCS contract period, Wave 2 must be launched by the middle of Spring 2013, well before the current school year closes. If the HCS is unable to complete recruitment of family participants during Spring 2013, with data collection occurring over the summer, Wave 2 of the study will be postponed till schools reopen in Fall 2013. Such a delay will potentially require further reductions to the proposed scope of the study.

An ICR package for the HCS was previously submitted to the Office of Management and Budget (OMB) and approval obtained for the first three years of planned data collection activities for the HCS (OMB control number 0925-0649 expiration date: January 31, 2015). Data collection for Wave 1 of the HCS occurred during the Spring and Summer of 2012. Based upon findings from Wave 1, and feedback by our Observational Study Monitoring Board (OSMB), an independent third-party oversight group that is required by the National Heart, Lung, and Blood Institute (NHLBI), modifications have been made to the study design and protocol that have resulted in this resubmission for Wave 2 of the study. The study changes will be cost-effective for the government, will slightly decrease participant burden, and will improve recruitment of families into the study, while minimally impacting the study aims and power.

Below is an overview of the major changes made to the study and reflected in this resubmission. If you have any questions related to these modifications, or to other aspects of the study, we would be pleased to participate in a call to hear your concerns and address these directly.

HCS OVERARCHING STUDY CHANGES:

Recruitment of Families: Based on the results of Wave 1, an alternative strategy has been developed for recruiting child participants and their parent(s)/ caregiver into the study. The original approach used land-line phone numbers which did not yield a representation sample. Thus a recruitment approach will be utilized for Wave 2 that involves recruiting schools in each community from which to identify potential study participants from among their Kindergarten to 8th grade (K-8) students. Schools will be asked to identify a member of their staff to serve as a school liaison to coordinate the recruitment process as well as help with other school-related study activities. In acknowledgement of the school's efforts on the study's behalf, each participating school and each school liaison will receive an incentive.

School Observations: As with the original HCS ICR submission, recruited schools will be asked to allow study staff to collect information on the school's physical activity and nutrition environments. Based upon the results from Wave 1, the respondent for the school's food environment questionnaire has been changed from a school food service staff person to the District Food Service Administrator/Manager. Additionally, questions on the school's physical activity and nutrition policies and practices will now be completed by the school liaison, as opposed to asking these questions of the School Principal during the key informant interview.

Sampling Strategy and Goals for Children: Under the school-based recruitment approach, the sampling strategy has been modified to sample children based upon school grade (K-8) versus age. The recruitment goal has been increased slightly (from 78 to 81 children per community) to allow for an equivalent number of children to be recruited from each grade (9 children in each of the 9 grades). With 81 children to be recruited in each community, the number and proportion of families selected to participate in the Enhanced Protocol data collection has also been adjusted, so that one child from each grade (9 children or 11%) will complete the Enhanced Protocol.

Reduction in the Number of Wave 2 Communities: The original HCS ICR submission detailed the steps for drawing a National Probability-based Sample (NPBS) and selecting certainty communities for Wave 2. This process has been completed and a total of 281 sampled census tracts selected. In some cases the same public high school was identified as being closest to the centroid of multiple selected tracts, reducing the total number of communities from 275 to 264. Power studies have been rerun with this new proposed number of communities (and the 81 children per community) and the results show a minimal loss of power (see Supporting Statement B, Attachment 3). Based upon the results of these power studies, a total of 264 communities and 81 children per community will be recruited for Wave 2 of the study.

Longitudinal Components of the Study: The remote follow-up interviews with families and key informants and the second in-person visit to 40 communities originally planned by the HCS have been eliminated due to budgetary and time constraints. The timeframe in which Wave 2 of the study will likely commence does not allow these longitudinal components to be fully completed within the study period; additionally, the elimination of these components allows fiscal resources to be redistributed to implement other study changes.

Other Changes: Additional changes have been made to the protocol to accommodate these larger overarching study changes or to streamline the data collection instruments to reduce

redundancies and participant burden, improve response rates, and identify the most appropriate respondent. These changes are reflected in the ICR resubmission.