

Supporting Statement A

for

**The Healthy Communities Study:
How Communities Shape Children's Health (NHLBI)**

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Information Collection Request for OMB Review

Supporting Statement for Paperwork Reduction Act Submissions: “The Healthy Communities Study: How Communities Shape Children’s Health”

Summary of the Healthy Communities Study (HCS)

The following text provides information on Wave 2 of the National Heart, Lung, and Blood Institute’s (NHLBI) planned “Healthy Communities Study (HCS): How Communities Shape Children’s Health.” An Information Collection Request (ICR) package 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, including Wave 1 of the study (OMB Notice of Approval 0925-0649 expiration date 1/31/2015). Four Communities were part of Wave 1 and the data was collected over the Spring and Summer of 2012; Wave 2 consists of 264 new communities. 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.

An overview of the major changes made to the study that are reflected in this resubmission is presented below.

New study aim: The Healthy Communities Study staff and its OSMB felt strongly about understanding how obesity is associated with programs and policies in population subgroups that are most at risk of being overweight/obese. As such, the study is purposely designed to oversample communities that have a large proportion of African American, Latino, and low-income residents. To reflect the importance of inclusion of at-risk groups, the following new study aim has been added: assess the associations between characteristics of programs/policies and BMI, diet and physical activity in children in communities that have a high proportion of African American, Latino, and/or low-income residents.

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 sample reflective of the community. Thus a recruitment approach will be utilized for Wave 2 that involves recruiting participants through interest forms sent home with students. In each community, interest forms will be sent home to students in two elementary schools and two middle schools asking parents/caregivers to complete the interest form and indicate whether they are interested in participating in the study. 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 new recruitment approach through schools, 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, reduce costs, improve response rates, and identify the most appropriate respondent. These changes are reflected in the ICR resubmission.

Ability to Address Study Aims with Proposed Study Design Changes:

The aims of the HCS are the same with the addition of a new third aim: to (1) determine the associations between characteristics of community programs/policies and body mass index (BMI), diet, and physical activity in children; (2) identify the community, family, and child factors that modify or mediate the associations between characteristics of community programs/policies and BMI, diet, and physical activity in children; and (3) assess the associations between characteristics of programs/policies and BMI, diet and physical activity in children in

communities that have a high proportion of African American, Latino, and/or low-income residents. In our original application we proposed a weighting scheme to provide nationally-representative estimates to answer the primary study questions. The revised design will produce a nationally-representative sample of communities (using the previously proposed weights) however this design is not designed to yield a nationally-representative sample of elementary and middle-school children. As such, the HCS design will enable the development of estimates of the associations between characteristics of community programs/policies and BMI, diet, and physical activity that will be applicable to a large, diverse group of elementary and middle school children located across the country. This approach is consistent with the design of many NHLBI-sponsored longitudinal cohort studies and will be sufficient to address the aims of HCS.

A limitation of the proposed study design is that the findings will not be representative of students across the country and thus findings will not be generalizable to all U.S. public elementary and middle school children. However, the HCS will be able to make conclusions such as “we found that in a large number of diverse low-income African American communities in this study, program and policy characteristics X, Y, and Z were related to BMI.” Changes have been made through Supporting Statements A & B to reflect that the sample of students is not nationally representative and that the findings will not be generalizable to public school elementary and middle school children.

The information is organized to respond directly to the 18 itemized subsections of Section A (Justification) of the Supporting Statement for Paperwork Reduction Act Submissions. A general description of the scope of work for the study is included below, as well as specific items in the Supporting Statement for Paperwork Reduction Act Submissions. Please refer to Attachment 1 for a list of study glossary of terms.

Rationale: Community programs and policies targeting childhood obesity are being implemented across the country, but their approaches not been systematically studied. There is natural variation in many aspects of these programs and policies, including intensity level, duration, funding, target population, and how they are implemented. However, no previous studies have examined these variations and how such aspects of community programs and policies are related to childhood obesity outcomes. Moreover, no studies have examined factors across a wide range of communities that may modify or mediate the associations between childhood obesity and programs and policies, such as community and family socio-demographic characteristics. The Healthy Communities Study (HCS) will address the need for a cross-cutting large study of community programs and policies and their relationship with childhood obesity.

The HCS is an observational study of communities that aims to (1) determine the associations between characteristics of community programs/policies and body mass index (BMI), diet, and physical activity in children; (2) identify the community, family, and child factors that modify or mediate the associations between characteristics of community programs/policies and BMI, diet, and physical activity in children; and (3) assess the associations between characteristics of programs/policies and BMI, diet and physical activity in children in communities that have a high proportion of African American, Latino, and/or low-income residents. For Wave 2, a total of 264 communities and over 21,000 children and their parents will be part of the HCS. A HCS

community is defined as a high school catchment. Elementary and middle school children and their parents will be enrolled in the study. Data will be collected on 81 children within each community. The study will examine quantitative and qualitative information obtained from community-based initiatives, community characteristics (e.g., school environment), and from child and parent assessments and measurements of physical activity levels and dietary practices of children, and children's and parent's BMI.

Design: The HCS employs a complex study design that includes a large, diverse group of communities across the country that will both (1) maximize the opportunity to identify what approaches and strategies are associated with a reduction in childhood obesity in communities with different characteristics, and (2) yield results that are applicable to communities across the United States, with particular focus on Hispanic/Latino, African American, and low-income children. The Wave 2 study design combines current/cross-sectional and retrospective data in 264 communities.

The 264 Wave 2 communities were selected using a hybrid approach that includes a National Probability Based Sample (NPBS) and a sample of communities selected with "certainty" that are known to be active in child obesity prevention work. The NPBS used a stratified sampling approach with probability proportional to the number of children aged 3-15 years to select 195 census tracts across the continental US. The strata were based on various factors including geographic region, income, race/ethnicity, urbanicity, and population size of the county.

A certainty community selection committee (CCSC) independently identified 86 areas to ensure the inclusion of communities with promising programs and policies aimed at reducing childhood obesity. Within each of the 86 geographic areas selected by the committee, a census tract was selected probabilistically.

The 281 sampled census tracts were then used to identify communities for Wave 2 of the HCS through identification of the closest public high school to the centroid of each selected tract. In some cases, there were multiple sampled census tracts that pointed to the same public high school – resulting in 264 unique communities.

Data collection: In each community, retrospective and cross-sectional data will be collected. The retrospective data will include children's height and weight extracted from medical charts and details of community programs/policies dating back ten years. The cross-sectional data will include in-home assessment of children's height and weight, diet, and physical activity. When available, the parents/caregivers height and weight will also be measured.

Data collection will consist of a two-step approach, with all study children receiving less detailed **Standard Protocol** measures (e.g., brief questionnaires). The **Standard Protocol visit** will take approximately 75 minutes to complete. A randomly selected subset of children (approximately 11%) will receive more detailed **Enhanced Protocol** measures (e.g., accelerometers, dietary recalls). The **Enhanced Protocol** will take approximately 180 minutes to complete, which includes two home visits, and use of an accelerometer for a one week period. Statistical modeling techniques will be employed to adjust measures from the Standard Protocol for bias and error using measures from the Enhanced Protocol. This two-step statistical modeling will improve the study's power without increasing burden for all participants.

Program/policy and environmental data will be collected through interviews with community key informants, participant perceptions of the school and home environments, interviews with school personnel, document review, GIS data, and direct observations of communities and schools, and other sources. Interviews with key informants will take 60 to 90 minutes to complete.

Timeline: The HCS is a five-year observational study, with Wave 2 data collection, analysis and reporting activities planned to occur over the next 3 years of the study. The timeline for Wave 2 activities is presented below:

- **Months 1 to 10** – Wave 2 study design and protocol development is finalized, the Office of Management and Budget (OMB) Information Collection Request and Institutional Review Board (IRB) approval packages are prepared and submitted. Additional activities related to field implementation (such as database development, development of the Manual of Procedures, training and quality control procedures, identification and hiring of field staff) are finalized and outreach and recruitment of School Districts begins in the first set of communities to be visited in the study.
- **Months 11 to 12** -- Schools within the recruited districts are recruited (upon OMB approval), and recruitment of families and key informants begins shortly thereafter.
- **Months 13 to 24** -- Wave 2 Data Collection begins; assessments in a total of 200 communities will be launched during this 12-month period, averaging 17 new communities per month. The assessments include the household visits, key informant interviews and community observations; medical record retrieval and abstraction begins shortly after all assessments are completed in each community. Additional activities conducted during this timeframe include quality assurance activities, ongoing data management, data analysis, and reporting, and preparation of interim reports.
- **Months 25 to 28** – Wave 2 Data Collection continues with the launch of the remaining 64 communities. The assessments include the household visits, key informant interviews and community observations; medical record retrieval and abstraction begins shortly after all assessments are completed in each community. Additional activities conducted during this timeframe include quality assurance activities, ongoing data management, data analysis, and reporting, and preparation of interim reports.
- **Months 29 to 36** – Wave 2 Data Collection is completed in all communities, including all medical record abstractions. Additional activities conducted during this timeframe include quality assurance activities, ongoing data management, data analysis, and reporting, preparation of interim and final reports, and publication of manuscripts.

The study design maximizes the use of the data and resources, and allows both cross-sectional and longitudinal BMI questions to be addressed.

The Research Team: The Research Coordinating Center leading the development and implementation of the HCS is Battelle Memorial Institute (Battelle). Battelle has formed a research team with key partners for each of the different but interrelated domains of the study. Investigators at the University of California at Berkeley are responsible for developing the tools and protocols for assessing dietary behaviors among child participants; investigators at the

University of South Carolina are responsible for developing the tools and protocols for assessing physical activity and sedentary behavior among child participants; investigators at the University of Kansas are responsible for designing the tools and protocols for the characterization of community programs and policies. The National Opinion Research Center (NORC) at the University of Chicago is responsible for recruiting schools, and Examination Management Services, Inc. (EMSI) is responsible for the medical record abstraction. Coordination of in-home data collections, methods, instruments, training, data analysis, and dissemination will take place at Battelle.

The study is funded by several National Institutes of Health (NIH) institutes and centers including the National Heart Lung and Blood Institute (NHLBI), the National Cancer Institute, the National Institute of Diabetes and Digestive and Kidney Diseases, the *Eunice Kennedy Shriver* National Institute of Child and Health and Human Development, and the Office of Behavioral and Social Sciences Research. In addition to the NIH scientific partners, the Centers for Disease Control and Prevention (CDC) and the Robert Wood Johnson Foundation (RWJF) are also non-funding partners in this study.

JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Responding to a Legislative Mandate: The objective of this information collection is within the NHLBI mandate described in the PHS Act, Section 421 (42USC 285b-3) and specifies provision of "investigation into the epidemiology, etiology and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases".

The National Institutes of Health (NIH), through the NHLBI, released a Request for Proposals (RFP) titled "Studying Community Programs to Reduce Childhood Obesity" in October of 2009. The RFP and subsequent project's study objectives are within the NHLBI's mandate, and the Institute has the unique capability to coordinate this study within 264 communities over an extended period of time as proposed. The NHLBI Board of External Experts (BEE) (see Attachment 2) and the NHLBI Advisory Council (see Attachment 3) reviewed the research initiative used to develop the RFP and approved it.

Why the need to collect these study data? Previous studies have not systematically examined community programs and policies implemented across the country and their relationship to childhood obesity. There is natural variation in many aspects of programs and policies, including intensity level, duration, funding, target population, and how they are implemented. However, no previous studies have examined this variation and how such aspects of community programs and policies are related to childhood obesity outcomes. Moreover, no studies have examined factors across a wide range of communities that may modify or mediate the associations between childhood obesity and programs and policies, such as community and family socio-demographic characteristics. The HCS will address the need for a crosscutting study of characteristics of community programs and policies and their relationship with childhood obesity.

Numerous observational studies have demonstrated an increased risk of obesity in communities with greater access to unhealthy foods, less access to healthy foods, and fewer opportunities to be physically active. These community characteristics tend to be associated with low-socioeconomic status and help explain the reason for the significant health disparities^{1,2} that are associated with higher obesity prevalence in such communities. The need to identify the most promising community approaches that all communities can use to reduce the obesity epidemic is urgent^{3,4,5, 6, 7, 8, 9}. The purpose of HCS is to assess the relationships between characteristics of programs/policies targeting childhood obesity and children's BMI, diet, and physical activity.

Why should the Federal Government sponsor this research? Children in the U.S. are at increased risk of developing obesity and consequently of developing chronic diseases earlier in life than previous generations. A comprehensive assessment of characteristics of programs and policies in communities to stop this epidemic, which affects all segments of children in the U. S. population, falls within the NIH mission to “seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.” The development and implementation of a study with a large, diverse group of communities across the country will allow us to capture the full range of characteristics of community programs and policies that are occurring across the country .

What information and evaluation components that relate to this research already exist? The major dietary behaviors contributing to energy imbalance among children have been extensively reviewed and identified.¹⁰ Low levels of physical activity have clearly made the population susceptible to excess weight gain as calories have become ever more available and inexpensive. The social and environmental determinants of obesity are less well studied, but the evidence is mounting. The HCS study design incorporates this research and allows the simultaneous examination of dietary behaviors, physical activity, and environments, including those modified

¹ Committee on Environmental Health. Policy Statement: The Built Environment: Designing Communities to Promote Physical Activity in Children. *Pediatrics*. 2009; 123(6):1591-1598.

² Beaulac, J., Kristjansson, E., Cummins, S. A systematic review of food deserts, 1966-2007. *Prev Chronic Dis*. Epub2009; 6(3):A105. Available from: http://www.cdc.gov/pccd/issues/2009/jul/08_0163.htm.

³ Swinburn BA, Caterson I, Seidell JC, James WP. Diet, nutrition and the prevention of excess weight gain and obesity. *Public Health Nutr*. 2004; 7(1A):123-146.

⁴ French SA, Story M, Jeffery RW. Environmental influences on eating and physical activity. *Annual Rev Public Health*. 2001; 22:309-35.

⁵ Ritchie LD, Hoelscher M, Sothorn M, Crawford PB. Position of the American Dietetic Association: Individual-, Family-, School-, and Community-Based Interventions for Pediatric Overweight. *J Am Diet Assoc*. 2006; 106:925-945.

⁶ Hills AP, King NA, Armstrong TP. The Contribution of Physical Activity and Sedentary Behaviours to the Growth and Development of Children and Adolescents: Implications for Overweight and Obesity. *Sports Medicine*, 2007, 37(6):533-545(13).

⁷ Must A & Tybor DJ. Physical Activity and Sedentary Behavior: A Review of Longitudinal Studies of Weight and Adiposity in Youth. *Int J Obes* 2005; 29: S84-S96.

⁸ Fulton JE, Dai S, Steffen LM, Grunbaum JA, Shah SM, Labarthe DR. Physical Activity, Energy Intake, Sedentary Behavior, and Adiposity in Youth. *Am J Prev Med* 2009; 37(1S): S40-S49.

⁹ Ortega FB, Ruiz JR, Sjörström M. Physical Activity, Overweight and Central Adiposity in Swedish Children and Adolescents: the European Youth Heart Study. *Int J Behav Nutr Phys Act*. 2007 Nov 19; 4:61.

¹⁰ Woodward-Lopez G, Ritchie L, Gerstein D, Crawford P, editors. *Obesity: Dietary and Developmental Influences*. Boca Raton: CRC Press; 2006.

through community programs and policies. This research is reflected in the three areas which comprise the study's core activities of: a) community and environmental assessments of health-related programs and policies impacting elementary and middle school aged children; b) physical activity assessments; and c) dietary behavior assessments. The protocol and instruments build on the foundation of existing research in these three separate areas.

A.2 Purpose and Use of the Information Collection

The purpose of HCS is to assess the relationships between characteristics of community programs/policies targeting childhood obesity and children's BMI, diet, and physical activity. This study will include 264 communities and over 21,000 children and their parents. Below is a description of the types of data that will be collected and examples of research questions that can be answered with the data collected.

Cross-sectional and Retrospective data: In each community, cross-sectional and retrospective data will be collected. Cross-sectional data will include in-person assessment of BMI, diet, and physical activity on a sample of children in each of the 264 communities. Retrospective data to be collected from all 264 communities will include the history of childhood obesity programs and policies and how they unfolded over the previous ten years in each community. Additionally, BMI trajectories for each child will be created by combining BMI measured during the in-person visit with BMI calculated from height and weight data abstracted from the children's medical records for a period dating back up to 10 years. Thus, data available for analysis from all communities includes information about community programs/policies targeting childhood obesity over the previous 10 years and children's height and weight for a 10-year time period.

Data collection protocols: There are two types of data collection protocols, **Standard** and **Enhanced** for both children/parents and communities.

1) Standard Protocol

a) Child/Parent Standard Protocol: Parents and children in all 264 communities will be assessed with the Standard Protocol during the in-home visit. The Standard Protocol visit includes height, weight and girth measurements of the child, height and weight measurements or reported measurements of the parents/caregivers when available, completion of general demographic and background questions, brief diet and physical activity behaviors questionnaires, and medical record abstraction to develop longitudinal children's BMI trajectories. We estimate that medical records will be obtained for approximately 70% of children in the sample. Please see Attachments 4 for the Family Recruitment Toolkit that will be utilized by schools to recruit families for the HCS; Attachment 5 for the household screening protocol; Attachment 6 for the household visit protocol for parents/caregivers (including the recruitment script, consent and the medical record release authorization forms, anthropometrics form, and the home interview); Attachment 7 for the household visit protocol for the second parent/caregiver (including the consent and anthropometrics forms); Attachment 8 for data collection protocol for parents/caregivers who refuse to participate in the study; and Attachment 9 for the

household visit protocol for children (including the assent and anthropometrics forms, and the home interview).

b) Community Standard Protocol: Within each community, 10-14 key informants will be interviewed to assess and document community programs and policies targeting childhood obesity and how they have evolved over the previous ten years. Key informants will consist of individuals from several key settings/sectors, including schools, healthcare organizations/coalitions, government, and non-profit/community organizations/service agencies. Please see Attachments 10 and 11 for the informational letter and brochure for key informants, and Attachment 12 for the key informant screening protocol and Attachment 13 for the key informant interview protocol.

Field interviewers will conduct a condensed five-item windshield survey (derived from the Neighborhood Attributes Inventory [NAI]) in the street segment immediately outside each participant's house during the home assessment (please see Attachment 14 for the modified windshield survey). The Battelle community liaison will also conduct assessments of the physical activity and nutritional environment in up to four schools (two elementary and two middle) per community from which the sample of children/families was recruited. These assessments include: (1) completing an observation form on the school's lunch period and requesting food service personnel to respond to 4 questions related to the lunch period; (2) conducting a modified Physical Activity Resource Assessment (PARA); and (3) a brief interview with a Physical Education (PE) instructor. Please refer to Attachments 15, 16 and 17 for the protocol for the school lunch period observations, the modified PARA, and the physical education instructor protocol respectively. Additionally, the Food Service Director/Manager at the School District level will be asked to complete a web-based survey on the food environment for each of the schools within their district that are recruited in the study. Please refer to Attachments 18 for the school food environment instrument. The school liaison at each school recruited in the study will also be asked to complete a web-based survey on the school policies and practices related to physical activity and nutrition. Please see Attachment 19 for the school physical activity and nutrition policies and practices instrument.

2) Enhanced Protocol

Child/Parent Enhanced Protocol: Approximately 11% of children within each community (i.e., one in nine children, one child for every grade from K-8) will receive an Enhanced Protocol that includes all the Standard Protocol measures plus more detailed measures of diet (i.e., two 24-hour dietary recalls) and physical activity (i.e., wearing an accelerometer during waking hours for one week and completing the Physical Activity Behavior Recall instrument).

Research Questions: The HCS is designed to address a variety of research questions that are both cross-sectional and longitudinal in nature. The main outcome variables of interest are BMI, diet, and physical activity behaviors in children. We expect to answer questions about how these variables are related to aspects of community programs and policies, which can be grouped into four broad areas: (a) intensity, (b) specific attributes, such as duration, funding, and target

population, (c) combinations of programs and policies, and (d) factors that modify or mediate associations with the outcome variables of interest.

These research questions can be answered with both cross-sectional and longitudinal data. Cross-sectional analyses can examine the association of characteristics of community programs and policies with BMI, diet, and physical activity at a single point in time on a sample of children in these large, diverse communities across the country using measured height and weight to calculate BMI. In longitudinal analyses, BMI trajectories can be modeled as a function of the intensity of community programs and policies within each community over the same period. Analyses can explore which attributes or combinations of programs and policies are most strongly associated with BMI, diet, and physical activity among children, and if these associations are modified or mediated by community, family, or child factors. Examples of the primary HCS research questions are provided below:

A. Research Questions Related to Community Programs/Policies

1. What intensity of community programs/policies is associated with BMI, diet, and physical activity behaviors among children? **(Cross-sectional)**
2. Are changes in intensity of community programs/policies associated with changes in BMI among children? **(Longitudinal)**

Answers to these questions can lead to a better understanding of how the intensity of community programs and policies targeting childhood obesity is associated with lower BMI, as well as protective diet and physical activity behaviors among children.

B. Research Questions Related to Specific Attributes of Community Programs/Policies

1. What attributes of community programs/policies are most associated with BMI, diet, and physical activity among children? **(Cross-sectional)**
 - a. For example, which of the following community program/policy attributes has the strongest association with childhood BMI: community program/policy duration, funding, or target population (e.g., targeting at-risk youth versus the general population)?
2. What attributes of community programs/policies are most associated with **changes** in BMI? **(Longitudinal)**

Answers to these questions can help provide insights into which specific attributes of community programs/policies are most essential in lowering childhood obesity.

C. Research Questions Related to Specific Combinations of Community Programs/Policies

1. What combinations of community programs/policies are associated with BMI, diet, and physical activity among children? **(Cross-sectional)**
2. What combinations of community programs/policies are associated with **changes** in BMI among children? **(Longitudinal)**

Answers to these questions will help address whether combinations of programs/policies – such as enhanced school programs in conjunction with expanded parks and recreational opportunities – have a stronger association with BMI, diet, and physical activity than one particular program.

D. Research questions related to Factors that Modify or Mediate Associations

1. What factors modify or mediate associations between community programs/policies and BMI, diet, and physical activity among children? **(Cross-sectional)**
 - a. For example, do community and family socio-demographic characteristics modify the associations between community programs/policies and BMI, diet, and physical activity?
 - b. Are community programs/policies that are associated with a lower BMI and protective diet and physical activity behaviors in children mediated through parent support for healthy eating and physical activity?
2. What factors modify or mediate associations between community programs/policies and **changes** in BMI among children? **(Longitudinal)**

Answers to these questions will help address whether factors such as greater availability of healthy foods and less availability of unhealthy foods at schools or the presence of parks and walking paths in a community modify the association between community programs/policies and BMI, diet, and physical activity among children.

Identifying Promising Practices in Preventing Childhood Obesity Will Be A Major Benefit of the Healthy Communities Study Results. Previously funded community efforts to prevent childhood obesity include both single-component interventions, such as reducing the price of fruits and vegetables, and multi-component interventions, such as Shape Up Somerville, to affect changes in adiposity, dietary intake, and/or physical activity.^{11,12,13,14} The CDC and the Institute of Medicine (IOM) have published recommendations for communities (e.g., the IOM reports on Preventing Childhood Obesity¹⁵ and the CDC Recommended Community Strategies and Measurements to Prevent Obesity in the United States¹⁶).

These national organizations have acknowledged, however, that the evidence base is relatively weak, and more data are urgently needed to develop stronger evidence-based recommendations. Few studies with robust designs exist that have examined change in adiposity as an outcome, such as is planned for the HCS. While many programs/policies are funded through national, state, or local initiatives, and have an evaluation component, these evaluations are variable in design and rigor. Documentation of the range and extent of efforts in which communities are investing to prevent childhood obesity is limited, and large-scale systematic evaluation using objective data, such as measured height and weight, do not exist. Comprehensive multi-component programs have the potential to make the greatest impact, but these have not been systematically examined. In addition, no studies have conducted analyses to determine the

¹¹ French SA. Pricing effects on food choices. *J Nutr.* 2003; 133:841S-843S.

¹² French SA. Public Health strategies for dietary change: schools and workplaces. *J Nutr.* 2005; 135:910-912.

¹³ James J, Thomas P, Cavan D, Kerr D. Preventing childhood obesity by reducing consumption of carbonated drinks: Cluster randomized controlled trial. *BMJ.* 2004; 328(7450):1237.

¹⁴ Laurence S, Peterken R, Burns C. Fresh Kids: the efficacy of a Health Promoting Schools approach to increasing consumption of fruit and water in Australia. *Health Promotion International.* 2007; 22(3):218-226.

¹⁵ Institute of Medicine. *Preventing Childhood Obesity-Health in the Balance.* Washington, DC: The National Academies Press; 2005.

¹⁶ Keener D, Goodman K, Lowry A, Zaro S, Kettel Khan L. *Recommended Community Strategies and Measurements to Prevent Obesity in the United States: Implementation and Measurement Guide.* Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009.

relative contribution of the various intervention components to the measured outcomes. Further, very few studies have examined the extent of implementation of various program and policy models and components, contextual factors that influence long-term impact, program sustainability, feasibility, or potential for widespread dissemination.

The study of the relative impact of different programs and policies across research studies has been limited by methodological differences and by differences in the study populations and locations. Very little is known about the minimum program/policy intensity or combination of approaches needed for measurable impact. In addition, little is known about the community factors and processes that are important to enable effective implementation and sustainability of promising program/policy approaches. The HCS will begin to investigate these questions by examining common themes across community programs and policies and linking them to obesity-related outcomes using a study design that maximizes data collected retrospectively and prospectively for 264 communities across the country and more than 21,000 elementary and middle school children .

Government Agencies Will Use the Healthy Communities Study Results: Results from the HCS will address the associations between characteristics of community programs/policies targeting childhood obesity and children’s BMI, diet, and physical activity. This information may influence decisions by federal, state, and local governments and organizations charged with improving children’s health (including the NIH, CDC, United States Department of Agriculture (USDA), and all state health departments across the U.S.), specifically how they develop and fund future policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals, meetings, and will be used for the development of future research initiatives targeting childhood obesity.

A.3 Use of Information Technology and Burden Reduction

Tracking System Software

The HCS will use a state-of-the-art system for data collection and management that maximizes data accuracy and minimizes participant burden. The tracking system software, PRECISE, has been developed for use in another large study (the NIH-funded National Children’s Study) and will be adapted for use by the HCS for its Information Management System (IMS). This IMS system will provide our team with the ability to recruit and track study participants throughout all years and waves of the study.

This software is designed to track and manage the recruiting activities and field visits to all participants and facilitates data transmissions from the field. The software has been tested for efficient operations, accuracy in data collection, and compliance with the Federal Information Security Management Act (FISMA) of 2002. It has also been found to work well with the data collection software, DatStat Illume, which has been used for the survey instruments and data collection forms. Illume works seamlessly with the IMS tracking software so that all recruitment, field management and data collection operations are accomplished efficiently.

Child/Parent Recruitment and Screening – The primary recruiting method for children and their families is through elementary, middle and/or K-8 schools. Battelle will utilize a sampling method with probability proportional to size to select up to 4 schools to approach for participant recruitment; where the measure of size is proportional to the fraction of the student population in the school that is either Hispanic/Latino or African American (depending on which strata the community represents). Schools that agree to participate in the study will receive a Toolkit with recruitment materials that can be shared with students’ families to provide them with information on the study, and an Interest Form to be completed by those families with children in grades K-8 that may be interested in participating in the study.

Contact information obtained through the Interest Forms will be loaded into the study database; if the home address is provided on the interest form, a catchment check will be conducted to ensure that the family resides in the designated communities. Telephone contact will be attempted to recruit families using CATI (Computer Assisted Telephone Interview) screener.

CATI screening calls to each household will be tracked using a proprietary automated tracking system. This system provides the phone interviewer with the initial contact information loaded into the system from the interest forms along with any additional information collected during the course of the phone call. The system automatically tracks the number of calls to a specific household and records the outcome for each call attempt. The telephone interviewer is able to see when the number of call attempts has reached the predetermined limit with no result, and can remove the number from the phone queue so that no household will be overburdened with phone calls and to contain recruiting costs. A five-call design is planned for each household. Screening information collected in an electronic CATI instrument is stored in a central database that is located in the Battelle Information Security and Compliance (BISC) center. The screening process is designed to exclude ineligible households quickly without making unnecessary use of the respondent’s time. Once the household is determined to match eligibility criteria, the gender and grade level of the children in the household are collected and matched with open cells for each gender and grade. The system randomly selects a child for participation in the study if more than one child is eligible. Once a child is selected, if the parent/caregiver agrees to participate, the telephone interviewer collects information about the household, including address, alternate phone numbers, the parent’s/caregiver’s name, the name of the most appropriate adult respondent, and other information that can be used by the field interviewer at the home visit. In the event that a person is partially screened, the telephone interviewer will record a good time to call the household back to schedule the next call. The case will come up for the telephone interviewer to call at the agreed upon time so the respondent is prepared for the call and the call is not placed at inappropriate times.

A study website has been created to provide general information on the study. This site will provide a lay-language study overview, a description of the roles for children and parents, a study timeline, answers to frequently asked questions, study contact information, and links to other relevant resources. All web pages will be §508 compliant for access by users with disabilities.

Scheduling Household Visits – Field interviewers’ schedules are accessible by the telephone interviewers who are conducting the screening and recruitment calls; once a family is eligible and agrees to the home visit, the telephone interviewer schedules the household visit and assigns

a field interviewer for that visit. The appointments are recorded in the central database, and then transmitted via secure web services to the laptop personal computer (PC) of the field interviewer who is assigned to call the household prior to the visit to confirm the appointments and conduct the visit. By scheduling household visits using an automated system, overbooking, missed appointments and unbalanced case assignments are avoided. For the participant, this allows for on-time appointments and the convenience of scheduling at suitable times.

Child/Parent Interviews during Home Visit: The field interviewers will arrive at the household visits equipped with laptop PCs that have Internet access via broadband cards. The IMS is accessible on the laptops via Internet access or locally using a remote data collection (RDC) component, in case there is no signal available to connect to the Internet. When that occurs, records are transmitted to the server and removed from the laptop as soon as Internet access is available. This eliminates the necessity of using paper forms when the Internet is not available. The field interviewer will use the field tracking system to view and record information about the household and prior household visits, which allows the visit to be conducted more efficiently. Redundant data collection will not occur because data collected to-date is available to the interviewer. Information recorded at the visit is directly sent to the main database allowing real-time reporting and case management.

During the household visit, the interviewer will administer the questionnaire from the laptop. None of the questionnaires will be available until the field interviewer has checked that the correct consent(s)/assent have been signed by all participants. The individual who signs the consent and medical record release authorization form must be the child's legal guardian.

Portions of the interview will be self-administered by the parent/caregiver and child and other sections will be administered by the field interviewer. The IMS will only show the survey sections that are appropriate to the visit; for example, if the child is younger than 8 years old, self-administered child questionnaires that are only given to children aged 8 or older will not be shown. The survey sections will be provided in the IMS so that they can be administered in an order that is most convenient for the household. For example, if the required sections are complete and the child cannot stay for the full visit, the child interviews can be administered before the parent/caregiver interviews. The anthropometric measurements of the child and the parent/caregiver will be recorded on a hard copy form by the interviewer and key-entered into the IMS prior to leaving the household; hard copy forms of the modified windshield survey will also be completed, and will be entered into the IMS at a later time after the visit has been completed.

As previously noted, one in nine respondents will be randomly selected to receive more detailed physical activity and nutrition measures (i.e., the Enhanced Protocol). The children will be asked to wear an accelerometer during waking hours for approximately one week to record the child's movement with minimal burden on the child or the parent/caregiver. Estimates of dietary intake of the children will also be obtained, using the children's version of the National Cancer Institute (NCI) Automated Self-Administered 24-hour Recall (ASA24™) – ASA24-Kids. The dietary recall will be self-administered. The field interviewer will log on and enter the child's ID, note the date and time the interview commences, and then turn over the computer to the primary respondent. The primary respondent, along with the secondary respondent, will use the

computer to enter the information prompted by the online mascot. The field interviewer will be trained to give a neutral introduction and clear instructions to the parent/caregiver and child regarding who is to respond and to encourage interchange to obtain the most accurate information about the child's food intake on the previous day. The field interviewer will return after 8 to 10 days to download data recorded from the accelerometer into the IMS, administer the Physical Activity Behavior Recall for the previous day, and have the respondent(s) self-administer the ASA24-Kids for a second time. When the accelerometer records are transferred to the server, they are processed into aggregate data that can be analyzed.

At each visit, the respondents are offered an incentive. The respondent will sign a paper receipt for the gift, but the incentive record is also recorded into the IMS for accurate tracking and to reduce the risk of overpayments, non-payments, or theft.

Key Informant Recruitment and Screening: The key informants will be selected such that they represent a variety of roles and sectors (e.g., school principal, chair of community coalition) and represent a wide array of interests within the community. Interviewing 10-14 key informants in each community will allow for a diverse set of perspectives and is cost-effective. Potential key informants that are to be screened are added to the system in one of two ways. Prior to entering a community, a list of potential key informants for that community will be compiled and entered into the IMS. During the recruitment call and during the interview, the key informant will be asked to provide contact information about others who are knowledgeable about community programs and policies targeting childhood obesity. The Battelle community liaison will then enter these contacts into the IMS as candidate key informants. When candidate key informants are added into the IMS they will either be linked to a community program/policy that has already been entered into the system, or a new community program/policy will be added to the IMS and the candidate key informant linked to it. If the program or policy has not yet been entered, the program/policy is both entered into the IMS and linked to the key informant.

The IMS will show a list of candidate key informants that have yet to be screened and, if the Battelle community liaison scheduled a screening call with that person, the date and time of the scheduled call is displayed. During the call, the community liaison can access the screening/recruitment script; they will also have access to data entry screens to assist in recording contact information about other candidate key informants. The community liaison will enter the outcome of each contact and screening call into the IMS.

Scheduling Key Informant Interview: Once a key informant is successfully screened, the Battelle community liaison will schedule a time for an in-person visit or telephone interview. The visit appointments are entered in a calendar in the IMS that shows all scheduled visits for that community. If it is not possible to conduct an in-person visit, a telephone interview will be scheduled instead. The Battelle community liaison will collect the preferred contact method for confirming the appointment (letter or email) and will verify that this information is correctly entered in the IMS. After the screening call has ended, a confirmation letter or email reminder will be sent to the key informant with the scheduled visit date and time. During the screening call, the Battelle community liaison will also request documents pertaining to the program or policy that the key informant represents and record the names of the documents that will be provided by the key informant in the IMS.

Key Informant Interview: Prior to the interview, if any documents provided by the key informant are received, the Battelle community liaison will locate the program/policy record that is linked to the key informant and pre-enter information about the program/policy in the system. Prior to beginning the interview, consent will be requested from the key informant to conduct the interview, and the response documented in the IMS.

During the key informant interview, the Battelle community liaison will launch a questionnaire from the IMS that gathers information about the key informant, their community, their organization, and related programs/policies. The IMS will show known physical activity and/or nutrition programs/policies that are already linked to this key informant and, if other information about the program/policy was pre-entered from documents received, it will be available through the IMS. The key informant will be asked about other programs, policies, and environmental changes in the physical activity and nutrition areas. If the key informant reports a new program/policy it will be added to the system and a questionnaire will be administered for that program/policy. The community liaison will enter the name of any documents provided during the course of the interview. Throughout the interview, the community liaison will ask for other candidate key informants and will enter as much information as is provided into the IMS, including contact information and related programs/policies. That candidate will be later considered for future recruiting.

At the end of the interview, the Battelle community liaison will provide the key informant with the incentive gift. The outcome of the interview and information about the incentive gift are recorded in the IMS.

A.4 Efforts to Identify Duplication and Use of Similar Information

The primary objective of the HCS is to assess the relationships between characteristics of community programs/policies targeting childhood obesity and children's BMI, diet, and physical activity. Although many programs and policies are funded or supported by national, state, and local initiatives, the evaluation components of these programs vary in design and rigor. Documentation concerning the range and extent of efforts in which communities are investing to prevent childhood obesity is limited and a nationwide assessment of community-based programs and policies aimed at battling childhood obesity is lacking.

Large observational studies such as NHANES and the National Children's Study (NCS) do not collect the same type of data that will be collected within the HCS. NHANES is a cross-sectional survey focusing on individuals, and it does not collect longitudinal data on diet, physical activity, height, and weight. The NCS is a longitudinal observational study focused on the growth, development, and health of children across the United States, following them from before birth until age 21 years. While the NCS will collect data on BMI, the main objective is not on childhood obesity and the researchers will not collect the level of detail on factors that are related to childhood obesity as the HCS. Importantly, neither NHANES nor the NCS collects information on community programs and policies related to childhood obesity or detailed community characteristics, both of which are key components of the HCS.

Because the NHLBI HCS is being conducted concurrently with the CDC's Division of Community Health's Targeted Surveillance and Biometric study(TS/BIO), both NHLBI and CDC's Division of Community Health worked together to provide additional comment here. Both agencies worked together to understand each study's purpose, methods and measures and aligned measures for demographics and key outcome variables related to physical activity, diet and obesity in children. The HCS overlaps with the proposed TS/BIO study for a portion of the population (children ages 4 to 15) and one of five TS/BIO core outcomes (obesity). These studies are complimentary in terms of the broad research questions they are addressing and their study designs. Contributing factors to obesity can be framed as a complex system in which behavior is affected by multiple individual-level factors and socioenvironmental factors. Both studies take a multilevel approach to better understand how demographic and contextual factors may be related to childhood obesity. The studies are seeking to understand the influence of structural interventions (e.g., modifications to the environment or policies) on obesity-related behaviors. The HCS is also assessing the relationship of characteristics of community programs on childhood obesity to BMI, diet, and physical activity outcomes. Both studies have the potential to inform decision makers and funders at the local and national levels. In terms of design, both collect or use varying levels of information (e.g., individual and community levels) at different time points. The HCS is an observational study that collects current and ten-year retrospective data of detailed individual, school, and program and policy characteristics that may be associated with BMI, diet and physical activity in children. The findings from the HCS will be applicable to broadly diverse communities, with a particular focus on Hispanic/Latino, African American, and low-income children. While HCS is a research study that focuses on childhood obesity, the CDC TS/BIO study is a program evaluation that assesses the effectiveness of specific Community Transformation Grants Program strategies for prevention and control of chronic disease by assessing change in a variety of core outcomes specified by the Patient Protection and Affordable Care Act (i.e., weight, diet, physical activity, tobacco use, emotional well-being and overall mental health) in adults and children. The TS/Bio study uses a successive independent samples design, in which data are collected from three different samples of respondents (adults and children) selected in Years 1, 3, and 5 from the geographic areas targeted for interventions in a subset of CTG Program awardees. The design allows monitoring changes in outcomes at the population-level over time, but does not allow monitoring of individual respondent-level changes over time. Findings from both the HCS and TS/BIO studies can jointly influence the field by elucidating how the broader contextual environment is related to childhood obesity.

A.5 Impact on Small Businesses or Other Small Entities

Physicians constitute the primary small business potentially burdened by the HCS. Physician's offices are requested to provide medical records on selected patients identified by the study. To observe the associations between characteristics of community programs and policies on childhood obesity rates over time, medical records for the most recent ten years will be requested from the primary care providers (PCP) of those participants that have consented to allow access to the child's medical record as indicated by providing a signed medical release form. From the medical charts we will abstract height and weight information (to calculate BMI) as well as any nutritional or physical activity related information that may be included in the record, and information on chronic medical conditions that may be related to obesity (such as diabetes) and associated medical prescriptions. Medical charts will be obtained from approximately 70% of the participants as it is anticipated that some participants will refuse to allow access to the child's records. This information is collected only once.

Participating parents will provide the study with contact information for their child's PCP (see Attachment 6 for the Medical Record Release Authorization form). EMSI data abstractors will obtain the medical charts by submitting a request form to the identified PCP. Estimated time required by the physician's office to comply with the chart request is 10 minutes, which covers reading the request, locating the medical chart, and providing the appropriate sections to EMSI. The study's budget includes payment of standard fees charged by PCP offices to perform this service. Refer to Attachment 20 for the medical record retrieval protocol.

Key informants from different sectors of the community, some of which may be small business entities, will be interviewed in each community. The key informants are identified in the pre-interview phase to have knowledge about community programs/policies related to nutrition, physical activity, and healthy weight of children. These key informants may include individuals from schools, health organizations/coalitions, local government, and non-profit, community organizations and service agencies. The key informants will be asked to provide electronic and/or hard copy materials on programs and policies in their community promoting physical activity, nutrition, and healthy weight among children and youth. Additionally, key informants will be interviewed either in person or over the phone using a scripted questionnaire of 60 to 90 minutes duration. As needed, telephone follow-up calls will clarify responses or seek further information. The study will provide an incentive worth \$10 to participating key informants to compensate them for their time. Although the amount is relatively small, we also expect that compliance with the information requests should be consistent with their organization's mission.

This information collection will not have a significant impact on any of these small entities.

A.6 Consequence of Collecting the Information Less Frequently

Data within the HCS cannot be collected less frequently because information on children's diet behaviors, physical activity, and BMI must be collected at a minimum of one time point in order to assess the relationship between programs and policies targeting childhood obesity and diet, physical activity, and BMI.

Collecting information less frequently than proposed would seriously compromise the study's ability to assess the relationship between programs and policies and diet, physical activity, and BMI.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The HCS will comply with the guidelines of 5 CFR 1320.5. The current protocol designed for the HCS does not include any special circumstance that would cause information collection to be conducted in a manner outside of the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

On November 30, 2012, Vol. 77, No. 231, pages 71426-714271, the Federal Register published NHLBI's notice. The Project Officer received two comments from the public:

- 1) The first comment stated there was no need to collect data from the Healthy Communities Study. The Project Office acknowledged receipt of the comment.

The Project Office believes that the HCS is a very important study. Many children in the U.S. are at a high risk of developing obesity, and consequently of developing chronic disease earlier in life than previous generations. A comprehensive assessment of community programs and policies to address this significant public health problem, which affects all segments of children in the U. S. population, falls within the NIH mission to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability."

- 2) The second comment was submitted by someone at the American Heart Association who requested copies of the protocol and proposed tools from the HCS. The Project Office acknowledged receipt of the comment and sent the protocol and proposed tools to the individual.

In 2008, members of the National Collaborative on Childhood Obesity (NCCOR) discussed the need to systematically study existing community efforts targeting childhood obesity. NCCOR is a public-private collaboration of four of the largest funders of childhood obesity research: the National Institutes of Health, Centers for Disease Control and Prevention, the Robert Wood Johnson Foundation, and the USDA. NCCOR's mission is "to improve the efficiency, effectiveness, and application of childhood obesity research and to halt – and reverse – the childhood obesity trend through enhanced coordination and collaboration." Members of NCCOR are part of the HCS Steering Committee and have contributed to the study design to

ensure that it does not duplicate other ongoing efforts, but rather complements other childhood obesity efforts. NCCOR endorses this study and has written a letter of support (Attachment 21).

The scientific merit of the Healthy Communities Study was reviewed at many steps including the final review by the Advisory Council of the NHLBI. This study was approved by the NHLBI Advisory Council on October 21, 2008. The NHLBI Advisory Council is composed of non-government health professionals and provides final review of NHLBI Review (see Attachment 3).

A Healthy Communities Study Observational Study Monitoring Board (OSMB) has been meeting periodically to review the progress and to advise on study design, procedures, data analyses, and participant burden. The OSMB has held several meetings and provided its input and expertise in the study aims and hypotheses, study design, sampling methodology, instrumentation, and recruitment strategies. OSMB members consist of six individuals with expertise in epidemiology, statistics, diet, physical activity, community measures, and childhood obesity. On August 20, 2012, the OSMB met and approved the recommendation to recruit participants into the study through elementary and middle schools by sending home interest forms with students for their families to complete.

The OSMB members are:

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The HCS design and data collection components have been developed within several Committees and Subcommittees that began meeting regularly in the fall of 2010. The subcommittees include an Executive Committee; a Steering Committee; a Design and Data Analysis Subcommittee; a Nutrition Behaviors and Data Collection Subcommittee; a Physical Activity and Data Collection Subcommittee; a Community Measurement Subcommittee; a BMI and Medical Record Retrieval Subcommittee; a Recruitment and Data Collection Subcommittee, a Quality Assurance/Quality Control (QA/QC) Subcommittee; a Public Image and Relations Subcommittee; a Publications, Presentations, and Ancillary Studies Subcommittee; and an Operations Committee. A listing of the subcommittee members is provided in Attachment 22.

A.9 Explanation of Any Payment of Gift to Respondents

Schools

Up to four schools (a combination of elementary, middle and/or K-8 schools) in each community will be invited to participate in the HCS. Recruited schools will provide assistance in reaching out to parents/caregivers who may be interested in taking part in the study; the principal will select a member of their staff to serve as the School Liaison who will assist the study team with the logistics of reaching out to parents and also assist with raising awareness about the study among the families of the children that attend their school as well as the broader community. The school liaison will be provided with a Recruitment Toolkit that contains information on the study, and a letter, brochure and Interest Form to send home with students. Students will be asked to return the completed forms to the School Liaison who will collate these forms and provide them back to the study team.

Additionally, schools will be asked to allow a researcher from the study team to visit the school to conduct observations of their school's physical activity and food environment and interview a physical education instructor. The School Liaison will be asked to compile information and complete a brief, web-based survey on school policies and practices related to physical activity and nutrition. In acknowledgement of the school's efforts on the study's behalf, each participating school will receive an incentive worth about \$150.00.

School Liaisons

To assist with the dissemination and collection of the Recruitment Toolkit materials, a school liaison from amongst the professional staff at each school will be identified by the school

principal. This individual will also serve as the “School Champion” for the study, helping raise awareness of the study in the school and community. To successfully function in this capacity, the selected individual must be highly regarded and trusted by both students and their parents. The prime responsibility for the liaison will be to serve as the point of contact for the study to parents/guardians and the students; this includes engaging students to take the informational materials and Interest Form to their homes and return the completed form back to the school, and responding to questions from parents/guardians on the study. Each liaison will collect the returned interest forms from students and provide these to the HCS team. The school liaison will also be asked to complete a web-based survey on the school’s physical activity and nutrition policies and practices. An incentive worth \$50 will be given to the respondent as a token of appreciation for their services.

Children and Family Members

Children will be encouraged to return the interest forms whether or not they are interested in participating in the study. A small incentive (valued at no more than \$1 per student) will be provided to each student who returns their completed interest form. The HCS will work with the school liaison to best implement the process for distributing the incentives for returning completed interest forms.

Once children and families agree to participate in the study, they will be provided with a larger incentive. It is anticipated that the Standard Protocol in-home visit will take on average 75 minutes to complete, while those participating in the Enhanced Protocol will require an additional 20 minutes during the first home visit, 35 minutes for the use of the accelerometer over a one week period, and another 50 minutes during the second home visit. The incentives will be explained to potential participants during recruitment over the telephone and as part of the informed consent process at the home visit. Proposed incentives are based on both the age of the child and the level of participation (i.e., Standard Protocol or Enhanced Protocol). A family with a child in grade K-5 engaging only in the Standard Protocol will receive, at the completion of the assessment, an incentive worth \$25 along with a small age-appropriate toy valued at \$5. For Standard Protocol families with a child in grade 6 or above, where the older child is expected to play a more active role in the interview, we will provide a \$15 incentive for the family and a \$15 incentive for the child. Families who agree to engage in the more involved Enhanced Protocol activity will receive an additional incentive in the form of a \$50 money order at the time of the second home visit. For these families, at the time of consent, data collection staff will explain that the accelerometer has to be returned, and the PABR and ASA24-Kids completed, to receive the additional incentive.

Community Key Informants

Community key informants knowledgeable of community programs and policies targeting childhood obesity will be asked to provide information on programs/policies, such as supplying relevant program documentation and completing a 60 to 90 minute in-person or telephone interview. An incentive worth \$10 will be given to the respondent as a token of appreciation after each data collection event.

Medical Providers

Medical record abstraction from physician offices will be coordinated by EMSI. Though participating physicians will not be compensated directly, their offices may be paid per individual office policy regarding fees to cover costs associated with providing the requested information. EMSI, based on previous experience in this area, has developed estimates with respect to the proportion of medical offices that require a fee, in addition to the estimated range of fees. This amount has been built into the subcontract budget submitted by EMSI. No other form of compensation (financial or otherwise) will be provided to collect this type of data.

Compensation for participation in research studies, particularly of healthy subjects, is not new and is seen by most as fair and appropriate, even for participants of minor age. Monetary incentives for older children (who have a concept and appreciation for monetary compensation) and the provision of a small toy as an incentive for younger children (who lack this conceptual ability) have been found to be a common practice and appropriate in research studies involving children.^{17,18} In addition, an incentive has been found to encourage timely recruitment and continued participation by subjects (thus, improving response rates) in non-clinical studies.¹⁹

There is also clear and consistent evidence that monetary remuneration significantly increases response rates to mail, telephone, and face-to-face surveys, and experts on survey methods recommend their use.^{20,21} Church (1993)²² and Singer and colleagues (1999)²³ have published meta analyses comparing the response rates of mail and interviewer-mediated surveys with and without monetary incentives. These studies have clearly shown that even a nominal gratuity increases response rates, and that the amount of the incentive is positively correlated with response rate.^{24,25,26,27} Previous research also suggests that monetary incentives may be especially effective in recruiting low-income and minority respondents. For example, analyses by Singer et al.²⁸ indicate that a \$5 incentive paid to a random half of households in a random digit dialed telephone survey brought a higher percentage of low-education respondents into the

¹⁷ Weise KL, Smith ML, Maschke KJ, Copeland HL. National practices regarding payment to research subjects for participating in pediatric research. *Pediatrics*. 2002; 110(3):577-582.

¹⁸ Bagley SJ, Reynolds WW, Nelson RM. Is a "wage-payment" model for research participation appropriate for children? *Pediatrics*. 2007; 119: 46-51.

¹⁹ Grady C. Payment of clinical research subjects. *Journal of Clinical Investigation*. 2005; 115(7):1681-1687.

²⁰ Dillman, DA. 2000. *Mail and Telephone Surveys*. New York, NY: John Wiley & Sons.

²¹ Sudman S. Mail surveys of reluctant professionals. *Evaluation Review* 1985; 9(3):349-360.

²² Church, AH. 1993. Estimating the effect of incentives on mail survey response rates: a meta-analysis. *Public Opinion Quarterly*, 57:62-79.

²³ Singer, E, Gebler, N, Raghunathan, T, Van Hoewyk, J, McGonagle, K. 1999. The effect of incentives on response rates in interviewer-mediated surveys. *Journal of Official Statistics*, 15: 217-230.

²⁴ Kropf, ME, Scheib, J, Blair, J. 1999. The effect of alternative incentives on cooperation and refusal conversion in a telephone survey. Presented at the 54th Annual Meeting of the American Association for Public Opinion Research, St. Petersburg, Florida, May 13-16, 1999.

²⁵ Hopkins KD, Gullickson AR. Response rates in survey research: a meta-analysis of the effects of monetary gratuities. *J Experimental Education* 1992; 61(1):52-62.

²⁶ Fox, RJ, Crask, MR, Kim, J. 1988. Mail survey response rate: A meta-analysis of selected techniques for inducing response. *Public Opinion Quarterly*, 52:467-491.

²⁷ Harvey, L. Factors affecting response rates to mailed questionnaires: A comprehensive literature review. 1987. *Journal of Marketing Research*, 29(3):341-353.

²⁸ Singer, E, Van Hoewyk, J, Maher, MP. 2000. Experiments with incentives in telephone surveys. *Public Opinion Quarterly*, 64(2):171-88.

sample. For our study, it will be important to include all sampled members of the selected communities, including low-income and minority households.

Finally, to serve as a comparison, several recent studies have provided a monetary incentive to respondents. For example, a CDC study entitled “Preventive Cardiac Health Care Knowledge, Beliefs, and Behaviors in Female Carriers of Duchenne/Becker Muscular Dystrophy” (OMB No. 0920-0718) provided \$5 to each of 1,477 women who participated in a mail survey. Another study entitled “CDC’s Cervical Cancer Study (Cx3) – An Intervention Pilot Study of HPV in Illinois NBCCEDP” (OMB No. 0920-0814) provided a monthly incentive valued at \$10 to clinic staff who completed a four-page survey each month for a year describing their clinic’s study participation. Additionally, a CDC study entitled the “Study to Explore Early Development (SEED)” (OMB No. 0920-0741) involved incentives to families with young children, many of which included children with autism or other developmental disabilities. In this longitudinal study, incentives ranged from \$25 included in the enrollment packet, to \$30 included in questionnaire packets, to \$80 for clinic visits.

A.10 Assurance of Confidentiality Provided to Respondents

Data Security: All HCS investigators and their institutions have agreed to comply with the Federal Privacy Act as part of their contractual agreement with NHLBI. The contract stipulates that research involving human subjects cannot be conducted until (1) the protocol has been approved by NHLBI; (2) written notice of such approval is provided by the Contracting Officer; and (3) completed Form HHS-596 certifying Institutional Review Board (IRB) review and approval of the protocol (Attachment 23).

All individuals participating in this study will be assured that the information they provide will not be released in a form that identifies individual respondents, unless required by law. No information will be reported by the contractor in any way that permits linkage to individual respondents. The study team is firmly committed to the principle that the protection of participants’ data obtained from questionnaires and existing records is of utmost importance. This principle is embedded throughout the process of gaining cooperation and obtaining approval. It holds whether or not any specific guarantee of data security was given at the time of the data collection, or whether or not there are specific contractual obligations to the client. The protection of participants’ data is an ethical responsibility of study staff and to ensure the security of participants’ data, ten specific security procedures are incorporated into each study. These procedures include:

1. All Battelle employees and subcontractors including office and data collection staff are required to sign an assurance of data security. This assurance contains a listing of the organization's steps to protect data and includes a pledge by employees and data collectors indicating that they will cooperate fully with these procedures. In addition, the data collectors' training manuals include a section on the ethics of data collection that stresses the importance of data security and privacy.

2. Unless specifically instructed otherwise for a particular project, employees are not allowed to abstract, collect or process data from a respondent whom they know personally.
3. Interviews are always to be conducted in the most private settings available. No individual other than the parent/caregiver should be present in the room, or listening on the telephone, during an interview. While sensitive questions are being answered in the home interview by children twelve years and older onto a computer laptop, the field interviewer will be collecting other information from the parent/guardian, using this time, for example, to take the parents/caregivers anthropometric measures and/or distribute the incentive. As necessary, the field interviewer will engage the parent/guardian in conversation until the child completes this section. The field interviewer will ensure that the parent does not see the questions or answers on the computer screen while the older child is completing these sections of the survey instrument.
4. Collected survey data, if gathered off-site, are mailed in separate envelopes from forms containing personal identifiers.
5. Survey data forms containing personal identifiers are kept in separate locked files or a locked room when not being used in routine survey activities. Forms with identifiers, such as face sheets, are kept separate from completed data collection forms or, if on data tape, from tapes with collected data.
6. Completed data collection forms are entered on the computer file without personal identifiers (that is, names, addresses, telephone numbers, social security numbers, etc.). On all data instruments, subjects are only identified by unique study identification numbers.
7. At the end of the survey performance period, the study manager arranges for proper storage or disposition of survey data depending on particular contractual requirements for storage or disposition.
8. The Battelle Institutional Review Board must approve all studies before any contact may be made with human subjects.
9. Reports and publications of collected data are presented in aggregate form only. The names or any other identifiers of participants are not made available to any person, group, or agency.

NORC, the subcontractor responsible for the school recruitment, collection of the interest form, and collection of the web-based survey data from school liaisons and District Food Service Managers/Administrators, places great emphasis on its reputation for integrity. NORC strives to maintain the highest standards of ethics, privacy and business conduct. All NORC employees, consultants, and subcontractors when representing NORC are expected to comply with NORC ethics, confidentiality and business conduct policies.

NORC has an obligation to implement appropriate security policies and procedures to protect the integrity, confidentiality, and availability of its customer, employee and, business partners data. NORC's security policies and framework are designed according to the NIST 800-53 standard and industry best practices. NORC written policies are designed to ensure the security, integrity and effective operation of the systems; to prevent the unauthorized exploitation of classified or sensitive data, systems, networks, or sites; to prevent any damage to or alteration of information technology hardware or software; and to minimize any disruption of operations, business interruption, data loss, or system overload.

EMSI is also committed to conducting business in compliance with all applicable laws, regulations, and customer requirements. Their written policies cover EMSI's general approach to compliance with the security regulations used by the industry as best practices to (1) ensure the protection, integrity and availability of all private and personal information EMSI creates, receives, maintains or transmits; (2) protect against any reasonably anticipated threats or hazards to the security or integrity of such information; (3) protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required; and (4) ensure compliance by its workforce. To enforce these policies, EMSI utilizes administrative, physical and technical safeguards.

Privacy Act: As stated above, in publications, the individual identities of participants are not disclosed, and data are reported only in the aggregate. Information obtained from the study will be included in the NIH Privacy Act Systems of Records Notice 09-25-0200, entitled, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD," published in the Federal Register, Volume 67, No. 187, September 26, 2002 (Attachment 24).

Human Subjects Protection: The Battelle IRB has conducted a review of the current study design and protocols and has approved this study. The IRB approval letter is included as Attachment 23.

A.11 Justification for Sensitive Questions

The HCS will collect sensitive information described briefly below along with a justification for inclusion in this study:

Maturity status of the child: The parent and child surveys collect information that may be considered sensitive by some respondents, including data concerning pubescent stage of the child. This information is required for the interpretation of changes in BMI, a critical component of the planned analyses.

Annual household income as an indicator of socioeconomic status (SES): Income has been related to obesity and, in most studies, children from families with a higher SES tend to have less

obesity. Because family income may influence participation in childhood obesity programs, it is critical to collect.

Household Participation in Federal Food Programs: Inclusion of a question to assess a household’s participation in a Supplemental Nutrition Assistance Program [SNAP] or Supplemental Nutrition Program for Women, Infants or Children (WIC) is critical in being able to characterize the HCS sample in comparison to the national population, improve the accuracy of classifying children and families by economic status, and assess whether SNAP and WIC participation may modify or confound the relationship between community programs and policies and outcomes of interest (e.g., diet behaviors, BMI).

Child Participation in Reduced Price or Free School Lunches as an indicator of socioeconomic status (SES): Children’s participation in reduced-priced or free school lunches is another indicator of the household’s socioeconomic status. As previously stated, income has been related to obesity and, in most studies, children from families with a higher SES tend to have less obesity. Although a question on family income is included in the household instrument, this question will serve as another measure, particularly of disposable income.

Pregnancy status: Girls 12 and older will be asked about pregnancy status. Pregnancy-related weight gain needs to be accounted for in analyzing change in BMI.

As described in Section A.10 (Assurance of Confidentiality Provided to Respondents), appropriate measures to safeguard respondent privacy have been instituted. In addition, both child and adult respondents will be informed that they can decline to answer any question that they do not wish to answer.

A.12 Estimates of Annualized Burden Hours and Costs

The burden estimates shown in Table A.12.1 are for 3 years of data collection. Table A.12.1 is followed by a description of type of respondent, the annualized costs to respondents, and an explanation of how the time estimates in Table A.12.1 were determined.

Table A.12.1 Estimates for Annualized Hour Burden Over 3 Years of Data Collection for the HCS*

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response (in hours)	Estimated total annual burden hours requested
Parents/Guardians (screening)	39,600	1	10/60	6,600
Parents/Caregivers	7,128	1	1.56	11,120
Second Parents	3,564	1	7/60	416
Parents/Caregiver who refuse to participate	880	1	10/60	147
Children	7,128	1	1.04	7,413
Key Informants (screening)	3,520	1	5/60	293

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response (in hours)	Estimated total annual burden hours requested
Key Informants	1,056	1	2.25	2,376
Food Service Personnel	352	1	5/60	29
District Food Service Administrator/Manager	88	1	30/60	44
Physical Education Instructors	352	1	15/60	88
School Liaisons	352	1	25/60	147
Physicians/medical secretaries	4,990	1	10/60	832
TOTAL	69,010			29,505

*The estimates in Table A.12.1 are based upon respondents in the 264 Wave 2 communities over 3 years of data collection.

The following interview time estimates are based upon experience in prior studies using similar measures and pretests of the HCS questionnaires on fewer than nine individuals.

Parents/Caregivers screening time estimates: Wave 2 sampling of households will be conducted through schools in the community; interest forms will be sent home with children in grades K-8 for their parents/guardian to complete indicating interest in learning more about the study and providing contact information. These forms will be used to develop the sample from which the study will draw upon. Of the 9 grades (K-8) from which we will be recruiting students and their families in each community, we are estimating that 50 parents/guardians will complete the Interest Form and complete the screening call (9 grades x 50 parents/guardians=450). Families will then be screened to confirm their eligibility for the study. Completion of the interest form and the screening telephone survey will take approximately ten minutes. Please refer to Attachments 4 and 5 for the Recruitment Toolkit and the Screening protocol respectively.

Parents/Caregivers and Children time estimates: In each of the 264 Wave 2 communities a total of 81 child/parent-caregiver pairs will be recruited to participate in the study. Thus, a total of 21,384 children and their parent/caregiver will be interviewed during the 3 years of data collection. Of these 21,384 child/parent pairs, approximately 89% will be assigned to the Standard Protocol while 11% (1 child from each of the 9 grades) will be assigned to the Enhanced Protocol. This corresponds to 72 participants under the Standard Protocol and 9 participants under the Enhanced Protocol. Please refer to Attachment 9 for the child protocol.

Second Parents time estimates: If the second parent is present during the home visit, we will consent the second parent and obtain their height and weight. This component is anticipated to last an average of 7 minutes. It is anticipated that a second parent will be available and provide consent for approximately 50% of the families visited. Please refer to Attachment 7.

Parents ‘who refuse to participate’ time estimates: We will contact and interview parents whose children were eligible, but opted not to participate in the study. A ten-minute survey will be administered in ten randomly selected households among those that refused to participate in each

community. Contact will be attempted with five "failed contact" and five "refusal" parents at the end of data collection in each community to assess potential bias due to non-response. The number of non-responders per community (n=10) was selected to provide sufficient data (pooled across all communities) to assess whether there are significant differences between responders and non-responders, and to make appropriate adjustments for such biases if they exist. Please refer to Attachment 8.

Key Informants screening time estimates: Approximately 10-14 key informants in each community will be selected to document the evolution of policies and programs aimed at reducing childhood obesity in their community. In each of the 264 communities, it is anticipated that approximately 40 potential key informants will need to be screened in order to identify on average 12 key informants that consent to take part in the study. Thus, a total of 10,560 (i.e., 40 x 264) key informants will be screened over the 3 years of data collection. The screening call is anticipated to take approximately 5 minutes. Please refer to Attachment 12.

Key Informants time estimates: We anticipate that 3,168 key informants across the 264 communities (i.e., 12 x 264) will take part in the study. The key informants who consent to participate will complete a recruitment telephone call (estimated at 15 minutes), gather and provide documentation on their programs/policies (estimated at 30 minutes), and complete in-person or remote interviews (between 60 and 90 minutes). Please refer to Attachment 13 for the key informant protocol.

Food Service Personnel time estimates: Food service personnel in up to two elementary and two middle schools in each of the 264 communities will be asked to provide information on the school lunch period to supplement the community liaisons' observations of the lunchroom. A total of 1,056 (i.e., 4 x 264) food service personnel will complete the interview questions on the lunch observation form, which are expected to take no more than 5 minutes. Please refer to Attachment 15.

District Food Service Administrator/Manager: The District Food Service Administrator/Manager will be asked to complete web-based surveys on the food environment for each of the recruited schools in the 264 communities that fall within their school district. A total of 264 (i.e., 1 x 264) Food Service Administrators/Managers will be asked to complete the web-based surveys for up to 4 schools (two elementary and two middle schools, or their K-8 equivalent). The web-based surveys for the 4 schools are anticipated to take no more than 30 minutes to complete. Please refer to Attachment 18.

Physical Education Instructors time estimates: The Physical Education (PE) instructor in up to two elementary and two middle schools, or their K-8 equivalent, in each of the 264 communities will be interviewed and may be asked to guide the community liaison on a brief walking tour of the school. The interview by the Battelle community liaison and brief walk is estimated to take a total of 15 minutes. A total of 1,056 (i.e., 4 x 264) PE instructors will complete survey questions. Please refer to Attachment 17.

School Liaison time estimates: The School Liaison will be asked to complete a web-based survey on the School Policies and Practices Related to Physical Activity and Nutrition for their recruited schools in the 264 communities. Up to 4 schools (two elementary and two middle

schools, or their K-8 equivalent) will be recruited in each community. A total of 1,056 (i.e., 4 x 264) School Liaisons will be asked to complete the web-based survey for their schools. The web-based survey for each school is anticipated to take no more than 25 minutes to complete, including the time to look up information and review documentation for the responses. Please refer to Attachment 19.

Physicians (medical secretaries) time estimates: One medical primary care provider (PCP) per child will be contacted to request the child’s medical charts (for which consent was provided by the parent). Parents will provide the study with contact information for their child’s PCP. EMSI staff will obtain the medical charts by submitting a request form to the PCP. Estimated time required by the PCP’s office to comply with the chart request is 10 minutes, which covers reading the request, locating the medical chart, and providing the appropriate sections to EMSI. The study will reimburse standard fees charged by PCP offices to perform this service. Please refer to Attachment 20 for the protocol for selecting the child and PCP for medical record retrieval.

We anticipate that the study will be able to obtain the medical records for only 70% of the 21,384 children (n=14,969), due to parental/guardian refusal to consent to release the medical record or difficulty in locating the medical office or the child's medical record.

The estimated annualized costs to the respondents of the study are shown in Table A.12.2. There are no direct costs to the respondents other than their time to participate. We assumed an hourly rate for the participants equal to the 2009 U.S. median hourly rate across all job categories and states (http://www.bls.gov/oes/highlight_2009.htm). Mean hourly wages for federal, state, and local jobs in the overall category of community and social services occupations were averaged to obtain a mean hourly wage for the key informant respondent. These wage estimates were taken from the Bureau of Labor and Statistics May 2009 National Industry-Specific Occupational Employment and Wage Estimates (<http://www.bls.gov/oes/current/oessrci.htm#99>). Using these estimates, the total annualized cost to all respondents for the study is \$379,525.

Table A.12.2 Annualized Cost to Respondents 3 Years of Data Collection for the HCS*

Type of respondents	Number of Respondents	Frequency of Response	Average Time per Respondents (in hours)	Hourly Wage Rate	Respondent Cost*
Parents/Guardians (screening)	39,600	1	10/60	\$15.95	\$105,270
Parents/Caregivers	7,128	1	1.56	\$15.95	\$177,364
Second Parents	3,564	1	7/60	\$15.95	\$6,635
Parents/Guardians who refuse to participate	880	1	10/60	\$15.95	\$2,345
Children	7,128	1	1.04	N/A	
Key Informants (screening)	3,520	1	5/60	\$25.96	\$7,606
Key Informants	1,056	1	2.25	\$25.96	\$61,681
Food Service Personnel	352	1	5/60	\$15.95	\$463
District Food Service Administrator/Manager	88	1	30/60	\$25.96	\$1,142

Type of respondents	Number of Respondents	Frequency of Response	Average Time per Respondents (in hours)	Hourly Wage Rate	Respondent Cost*
Physical Education Instructors	352	1	15/60	\$15.95	\$1,404
School Liaisons	352	1	25/60	\$15.96	\$2,345
Physicians/medical secretaries	4,990	1	10/60	\$15.95	\$13,270
TOTAL	69,010				\$379,525

**The estimates in Table A.12.2 are based upon respondents in the 264 Wave 2 communities over 3 years of data collection. The reported and calculated numbers differ slightly due to rounding.

A total of 264 communities will be sampled during Wave 2 of the study with 81 child/parent pairs recruited from each community.

Given that older children will be able to complete more of the interview on their own than younger children, burden for parents and children will vary depending on the age of the child. Thus, the average time per response used to calculate burden (Table A.12.1) does not represent any one participant's average response time, but rather, an average of response times over all ages. Table A.12.3, below, shows the variation in child and parent/caregiver involvement on average (in minutes) by protocol type (Standard and Enhanced) and age of the child.

Table A.12.3 Variation in Child and Parent/Caregiver Involvement in Data Collection Activities (in minutes) by Protocol Type and Age of Child

PROTOCOL TYPE	TOTAL TIME (minutes)				AVERAGE TIME PER RESPONSE*
	AGE OF CHILD				
	4-5 YEARS	6-8 YEARS	9-11 YEARS	12-15 YEARS	
Standard Protocol, Parent/Caregiver:	88	88	88	67.5	83.44
Standard Protocol, Child:	29	48.33	55	58	50.56
Enhanced Protocol**, Parent/Caregiver:	199.5	199.5	199.5	84.0	173.83
Enhanced Protocol**, Child:	108.5	158.83	165.5	168.5	157.61

*The average time per response is calculated using the weighted average based upon the proportion of children in each age range.

**Please note that the Enhanced Protocol calculation includes the burden for recruitment in the study, scheduling of the home visit, the first visit to the home, the use of the accelerometer over a 7-day period, and the second visit to the home.

Table A.12.4 and Table A.12.5 provide an overview of the components of the Standard and Enhanced Protocols, respectively, with the estimated duration of each component for the home visits. Note that some components will occur simultaneously during the home visit and others will occur less frequently (e.g., not all households will have both parents/caregivers available or willing to allow their height/weight to be measured). Therefore, the aggregated time for all protocol components is higher than the total average time allotted for the Standard and Enhanced baseline visits.

Standard Protocol time estimates for children/parents: The Standard Protocol visit, which includes an in-home assessment to measure height and weight and complete questions on physical activity and diet, is anticipated to take on average 75 minutes (Table A.12.4).

Table A.12.4 Estimated Duration of Each Standard Protocol Component for the Home Visit

Protocol Type	Visit Component	Sub-components	Estimated Duration	
			Minutes	Hour
Standard Protocol	Household Visit			
	Consent	Parent/Caregiver Consent	15	0.25
		Medical Record Release		
		Child Assent (≥ 8)	10	0.17
	Survey: Socio-Demographic, Background, Exposure	Community P/P Exposure	15	0.25
		Demographic/Socio-Economic		
		Child birth details		
		Medical Insurance/History		
	Survey: Physical Activity (PA)	Child Behaviors	22.5	0.38
		PA Parent/Caregiver Survey		
		PA Behavior Recall (PABR)		
	Survey: Nutrition Behaviors	PA Child Survey	21	0.35
		Domains 1-9		
	Anthropometrics	Parent/Caregiver 1	3.5	0.06
Parent/Caregiver 2 Consent & Measurements		7	0.12	
Child (Height/Weight/Girth)		6	0.10	
Distribute Incentive		1	0.02	
TOTAL ESTIMATED DURATION OF ALL PROTOCOL COMPONENTS:		101	1.68	
AVERAGE TIME ALLOTTED FOR STANDARD PROTOCOL VISIT**:			75	1.25
**NOTE: Some protocol components will occur simultaneously, while others will occur less frequently (e.g., not all households will have both parents/caregivers available or willing to allow their height/weight to be taken); therefore the aggregated time for all individual protocol components (101 minutes) is higher than the total average time allotted for the standard protocol baseline (75 minutes).				

Enhanced Protocol time estimates for children/parents: The Enhanced Protocol will include the following in addition to the Standard Protocol measures: (1) wearing accelerometers for one week to objectively assess physical activity; (2) two 24-hour dietary recalls (via the ASA24-Kids) to assess dietary intake in more detail; and, (3) the Physical Activity Behavior Recall (PABR) instrument.

Participants will wear the accelerometer during waking hours for seven consecutive days on the waist using a belt. The ASA24-Kids will be administered to capture foods and beverages consumed during a 24-hour period. For children younger than six, the parent/caregiver will be asked to complete the recall; children aged between six and 11 years will complete the recall with the assistance of the parent/caregiver; and children aged 12 and over will complete the recall with input from the parent/caregiver if required. The ASA24-Kids will take approximately 30 minutes to complete at each visit. The first dietary recall will be administered during the first home visit (when the accelerometer is distributed) and the second will be conducted 8 to 10 days later during the second home visit (when the accelerometer is retrieved). At the second visit, a physical activity behavior recall (PABR) will also be completed to collect detailed information regarding a child's participation in specific forms of activity on the previous day. For each of these activities, the PABR captures the intensity at which the child did the activity, the time spent in the activity, where he/she did the activity, who the child did the activity with, and the specific form or type of activity performed. Children will complete the PABR with the help of their parents/caregiver.

We anticipate the duration of the first and second home visit to be on average 145 minutes, with an additional 35 minutes for the use of the accelerometer during the week between home visits (Table A.12.5).

Table A.12.5 Estimated Duration of Each Enhanced Protocol Component for the Home Visit

Protocol Type	Visit Component	Sub-components	Estimated Duration		
			Minutes	Hour	
Enhanced Protocol (components included in Standard Protocol)	Household Visit 1				
	Consent	Parent/Caregiver Consent	15	0.25	
		Medical Record Release			
		Child Assent (≥ 8)	10	0.17	
	Survey: Socio-Demographic, Background, Exposure	Community P/P Exposure	15	0.25	
		Demographic/Socio-Economic			
		Child birth details			
		Medical Insurance/History			
		Child Behaviors			
	Survey: Physical Activity (PA)	PA Parent/Caregiver Survey	22.5	0.38	
		PA Behavior Recall (PABR)			
		PA Child Survey			
	Survey: Nutrition Behaviors	Domains 1-9	21	0.35	
	Anthropometrics	Parent/Caregiver 1	3.5	0.06	
		Parent/Caregiver 2 Consent & Measurements	7	0.12	
Child (Height/Weight/Girth)		6	0.10		
Distribute Incentive		1	0.02		
Enhanced Protocol (components not included in Standard Protocol)	Accelerometer Initiation		2.5	0.04	
	Dietary 24 hour Recall (ASA24)		30	0.50	
	Total Average Time Allotted for Enhanced Protocol Visit 1**:		95	1.58	
	During Week in Between Visits				
	Use of Accelerometer for 1 Week		35	0.58	
	Household Visit 2				
	Distribute Second Incentive		1	0.02	
	Collect Accelerometer		1	0.02	
	Dietary 24 hour Recall (ASA24)		30	0.50	
	Physical Activity Behavior Recall (PABR)		12	0.20	
	Total Average Time Allotted for Enhanced Protocol Visit 2**:		50	0.83	
	TOTAL ESTIMATED DURATION OF ALL PROTOCOL COMPONENTS:		212.5	3.54	
	AVERAGE TIME ALLOTTED FOR ENHANCED PROTOCOL VISIT**:		180	3.00	
	**NOTE: Some protocol components will occur simultaneously, while others will occur less frequently (e.g., not all households will have both parents/caregivers available or willing to allow their height/weight to be taken); therefore the aggregated time for all individual protocol components (212.5 minutes) is higher than the total average time allotted for the enhanced protocol baseline (180 minutes).				

A.13 Estimate of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no direct costs to record keepers or respondents other than their time to participate.

A.14 Annualized Cost to the Federal Government

The annualized cost of monitoring the project by NHLBI is estimated at \$109,000. The average annualized cost (contracts and monitoring by NHLBI) to the U.S. Government for information collection is \$6,377,000. This information is itemized in the Table A.14.1.

Table A.14.1 Estimate of Annualized Cost to the Government (in Thousands)

Type of Cost	Contract	Other	Total
Study Mgmt & Operations	\$5,948	\$320	\$6,268
Monitoring		\$109	\$109
Total	\$5,948	\$429	\$6,377

A.15 Explanation for Program Changes or Adjustments

This study represents a revision for The Healthy Communities Study (OMB control number 0924-0649, expiration date 01/31/2015).

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 from the HCS Observational Study Monitoring Board (OSMB), an independent third-party oversight group that is required by the NHLBI, modifications have been made to the study design and protocol that have resulted in this revision for Wave 2 of the study. The study changes will be cost-effective for the government, will 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, which are reflected in this revision

New Study Aim: The Healthy Communities Study staff and its OSMB felt strongly about understanding how obesity is associated with programs and policies in population subgroups that are most at risk of being overweight/obese. As such, the study is purposely designed to oversample communities that have a large proportion of African American, Latino, and low-income residents. To reflect the importance of inclusion of at-risk groups, the following new study aim has been added: assess the associations between characteristics of programs/policies and BMI, diet and physical activity in children in communities that have a high proportion of African American, Latino, and/or low-income residents.

Recruitment of Families: Based on the results of Wave 1 implementation, an alternative strategy has been developed for recruiting child participants and their parent(s)/ caregivers into the study. The previous method included purchasing a list of contacts (names, addresses and phone

numbers) through infoUSA for a random sample of families with land-line phones living within the public high school catchment area that were expected to have children. The current literature suggests that the fraction of families across the US that have land-line phones has diminished significantly over time, and that there is a disproportionate fraction of minority families that use cell-phones exclusively (i.e. these families would not be represented in this sample). Wave 1 results indicated that this strategy yielded a sample that was not always reflective of the selected community with respect to race-ethnicity; furthermore, over 30 percent of the telephone numbers were disconnected, while a further 20 percent refused to participate, often before recruiters could provide any information on the study.

Therefore, the HCS has developed a recruitment approach for Wave 2 of the study that involves identifying and recruiting schools from each community in order to identify potential study participants from among their Kindergarten to 8th grade (K-8) students. Schools will be provided with a recruitment toolkit that includes Study Interest Forms to send home with students for parents/guardians to complete; the schools will then collect and send the completed forms to HCS research staff. Completed interest forms will be used to develop the sampling pool from which to contact families by telephone and schedule their in-home data collection visit.

The change in recruitment approach along with the emphasis on over recruiting at-risk children (African American, Latino, and low-income children) has resulted in the sample of students no longer being nationally representative and the findings will not be generalizable to U.S. public school elementary and middle school children. The project team and the study's OSMB felt that it was extremely important to focus recruitment efforts on those children who are most at risk. The change in the recruitment approach does not affect the study's ability to answer its main study questions. Throughout Supporting Statements A & B changes have been made to clarify that the sample of students is not nationally representative and that the findings will not be generalizable to U.S. public elementary and middle school children.

School Liaison: As part of the revised recruitment plan, schools will be asked to identify a member of their staff to serve as a school liaison. The school liaison will be responsible for coordinating the recruitment process, assisting with arrangements for study staff to visit the school, and completing a web-based survey on the school's physical activity and nutrition policies and practices. The burden for completing this collection of information by the school liaison has been estimated at 25 minutes.

Incentives for Schools and School Liaisons: In acknowledgement of the school's efforts on the study's behalf, each participating school will receive an incentive worth \$150.

School liaisons will also receive an incentive worth \$50 to thank them for their efforts.

District Food Service Administrator/Manager: In order to obtain the information on the school's food environment, the original ICR submission had included a self-administered questionnaire that was to be completed by food service personnel at each school. Results from Wave 1 indicated that this individual may not be the most knowledgeable to complete this questionnaire since decisions and policies regarding the school's food environment are often directed at the

district level. Therefore, the District Food Service Administrator/Manager will be asked to complete web-based surveys for each recruited school in that district on the food environment. The burden for completing this collection of information by school liaisons has been estimated at 30 minutes.

Sampling Strategy and Goals for Recruitment: Under the revised recruitment approach, the sampling strategy has been modified to sample children based upon school grade versus age, and to restrict the sample to children in K-8 grades. Sampling by grade (versus age) will simplify the study's ability to meet recruitment goals. While the majority of the children in K-8 grades are anticipated to be within the 5 to 14 age range, the protocol allows for the possibility of children aged 4 and children aged 15 to be included in the study should they be in the targeted grades. As there are a total of 9 grades (K-8 grades) from which to recruit children, 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 per grade). 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 to be taken for drawing a National Probability-based Sample (NPBS) and selecting certainty communities for Wave 2. As originally proposed, 195 census tracts were selected as part of the NPBS. A Certainty Community Selection Committee (CCSC) was convened to select approximately 80 certainty communities. The CCSC ultimately selected a total of 86 communities for inclusion in the Wave 2 sample. The 281 sampled census tracts were then used to identify communities for the HCS through identification of the closest public high school to the centroid of each selected tract. In some cases, there were multiple sampled census tracts that pointed to the same public high school catchment area – which reduced the total number of communities to 264. Power studies have been rerun with this new proposed number of communities (and the 81 children per community), and the results show that the reduction from 275 to 264 communities translates to a 2.5 percent loss in power for the cross-sectional binary response model, a 1.4% loss in power for the cross-sectional BMI model, and no loss in power for the retrospective longitudinal BMI model for the HCS (see Supporting Statement B, Attachment 3). Based upon the results of these power studies, and the minimal loss of power for the study, a total number of 264 communities will be visited and 81 children (9 per grade) will be recruited in Wave 2 of the study.

Longitudinal Components of the Study: Certain longitudinal data collection components that were originally planned by the HCS have been eliminated due to budgetary and time constraints. The data collection plan in the earlier ICR submission included remote follow-up interviews with families and key informants, and a second in-person visit in 40 communities to repeat the assessments conducted during the first visit. Due to the timeframe in which Wave 2 of the study will likely commence, these longitudinal components cannot be fully completed within the study period. Furthermore, the reduction in the study's longitudinal components allows fiscal resources to be redistributed to implement other study changes identified below (such as the change to the recruitment strategy). Therefore both the remote follow-up and the second in-person visit have been eliminated from the study.

Wave 2 of the HCS will still involve retrospective data collection, including the unfolding of programs/policies in a community over the past ten years and the abstraction of children's height and weight from their medical records in order to develop longitudinal BMI trajectories.

Recruitment response rates: We have added text to further clarify the recruitment process and expected recruitment response rates for school districts, schools, and students.

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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, decrease costs, improve response rates, and identify the most appropriate respondent. These changes are reflected in the ICR revision.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The Healthy Communities Study will collect data for Wave 2 of the study after obtaining OMB approval. Battelle staff will analyze the data in a timely manner after the necessary data cleaning has been done and after data quality control procedures have been verified.

Overall Data Tabulation and Publication Plans: We have formed a Presentation, Publications, and Ancillary Studies (P&P) Subcommittee that will oversee and direct the manner in which data will be tabulated and presented at lay and scientific sessions and submitted for publication in peer-reviewed journals. A series of publications are being planned to present and announce the plans, progress, and findings of the study. These publications will fall into three broad areas of results:

1. Publications documenting the key design elements of the study design;
2. Publications regarding the development of measures, procedures, processes and community engagement; and
3. Publications reflecting on the overall goal of finding and reporting on the associations between characteristics of community programs/policies and BMI, diet, and physical activity outcomes in children.

General Statistical Analysis Plans: The general analysis approach will include production of various summary tabulations, as well as statistical modeling to assess program/policy characteristics most associated with reductions in childhood obesity rates. Cross-tabulations will summarize data by a number of different program/policy characteristics, including type of organization, years of funding, level of funding, community average household income, gender/race/ethnicity distribution, etc. We will design a core set of tabulations that will be updated on a regular basis throughout the study (e.g., on a quarterly basis). The content of this set of tabulations will be dynamic, with new summaries added as new analysis ideas arise and summaries dropped if they are not providing valuable insights. The statistical analysis plan also will specify the regression models planned to identify program and community characteristics associated with significant reduction in childhood obesity rates.

Our sampling approach builds on well-developed statistical methodology, and integrates the concepts of epidemiological study design and data analysis with missing covariates that our team developed for the National Children's Study (NCS), and which are being pursued by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), CDC, and EPA. As stated earlier, our approach relies on nested stages of sampling, where each successive stage of sampling uses a subset of study participants selected in the previous stage.

Our design allows us to generate longitudinal BMI trajectories on a random sample of children within each community. These trajectories can be modeled as a function of the time-series of standardized community scores that we construct to rate the strength of obesity prevention/treatment programs and policies within each community. We will be able to capture a series of age-specific cohorts across the sample of communities involved in the study with sufficient sample size in each cohort to ascertain the association of different strategies to trends in childhood obesity.

Importance of Dissemination of Findings: Sharing of study objectives and plans allows potential and current participants to learn more about the project that they are either considering becoming involved in, or in which they have already enrolled. Providing this information should lead to higher participation rates. Likewise, sharing of results allows important findings to be transmitted to various stakeholder groups and programs around the country.

NHLBI Technical

Following approval of all plans and reports by NHLBI and any peer reviewers, we will post these approved materials on a public Website with communication to NHLBI and funding partners and all community programs that have won federal grants related to childhood obesity, and to local and state health departments. We will review the activity of users coming to the Website each month. Based on the reports of Website usage, Battelle will plan further ways to make the Website most effective in the distribution of study information and results. Further, results from the HCS will be published in appropriate scientific journals, presented at scientific meetings, and will be used for the development of future research initiatives and creation of opportunities targeting childhood obesity.

Timeline: The HCS is a five-year observational study, with Wave 2 data collection, analysis and reporting activities planned to occur over the next 3 years of the study. The timeline for Wave 2 activities is presented below:

- **Months 1 to 10** – Wave 2 study design and protocol development is finalized, the Office of Management and Budget (OMB) Information Collection Request and Institutional Review Board (IRB) approval packages are prepared and submitted. Additional activities related to field implementation (such as database development, development of the Manual of Procedures, training and quality control procedures, identification and hiring of field staff) are finalized and outreach and recruitment of School Districts begins in the first set of communities to be visited in the study.
- **Months 11 to 12** -- Schools within the recruited districts are recruited (upon OMB approval), and recruitment of families and key informants begins shortly thereafter.
- **Months 13 to 24** -- Wave 2 Data Collection begins; assessments in a total of 200 communities will be launched during this 12-month period, averaging 17 new communities per month. The assessments include the household visits, key informant interviews and community observations; medical record retrieval and abstraction begins shortly after all assessments are completed in each community. Additional activities conducted during this timeframe include quality assurance activities, ongoing data management, data analysis, and reporting, and preparation of interim reports.
- **Months 25 to 28** – Wave 2 Data Collection continues with the launch of the remaining 64 communities. The assessments include the household visits, key informant interviews and community observations; medical record retrieval and abstraction begins shortly after all assessments are completed in each community. Additional activities conducted during this timeframe include quality assurance activities, ongoing data management, data analysis, and reporting, and preparation of interim reports.
- **Months 29 to 36** – Wave 2 Data Collection is completed in all communities, including all medical record abstractions. Additional activities conducted during this timeframe

include quality assurance activities, ongoing data management, data analysis, and reporting, preparation of interim and final reports, and publication of manuscripts.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

There is no need to not display the expiration date for OMB approval of the information collection.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are sought.