1. **General Information:**

   PI: Steven Gortmaker, PhD

   Study Title: Study on Out of School Nutrition and Physical Activity Environments

   IRB NO: 18046

2. **Study Objectives**

   a. **Study Aims/Objectives/Hypotheses:** This study was designed as a community based participatory research intervention and dissemination project focused on improving nutrition and physical activity of children and youth in multiple out of school time settings in the Boston community: the “Out of School Nutrition And Physical activity intervention” (OSNAP). We worked to design and conduct research to tailor out of school time intervention materials so they are applicable to various settings in Boston, are efficient in that minimal resources and time are used, and are useful to participants. The primary hypothesis was: to determine if the Out of School Nutrition And Physical activity intervention (OSNAP) yields greater improvements in the primary outcomes of minutes of moderate and vigorous physical activity among children and youth in intervention sites compared to control sites. Secondary objectives: to determine if the OSNAP intervention yields greater improvements in the intervention sites in time of student engagement in physical activity, improvements in snacks and beverages (less sugar sweetened beverages, water as primary drink, fruits and vegetables, less trans fats), and less screen time compared to control sites.

3. **Study location:**

   a. **Study sites:** Out of school time programs serving youth ages 5-12 in Boston.

   b. **Site-specific regulations/customs impacting this study if different from the U.S. (if applicable):** N/A

   c. **Principal Investigator’s experience conducting research at study site(s) and familiarity with local culture:** The Principal Investigator (PI), Steven Gortmaker, Ph.D., is a Professor of the Practice of Health Sociology in the Department of Society, Human Development and Health (SHDH) and the Director of the Harvard Chan School of Public Health Prevention Research Center on Nutrition and Physical Activity (HPRC). Dr. Gortmaker has a strong track record in community-based participatory research, intervention design, statistical evaluation methods, and development of measures of physical activity and dietary measures for children and youth. He has led the Harvard PRC over the past 15 years and been PI on multiple community based participatory research projects over the past three decades, including Planet Health, Eat Well and Keep Moving, Play Across Boston, the evaluation of the Maine Youth Overweight Collaborative, and the YMCA-Harvard Afterschool Project. Dr. Gortmaker has also
conducted extensive studies of chronic conditions in children, including the first to identify passive smoke as a significant cause of childhood asthma, the first United States study to identify television viewing as a major cause of increasing obesity in children, and the first to document increasing pediatric obesity in the United States. He has published more than 215 papers in peer-reviewed journals, and co-authored school curricula in widespread use (Planet Health, Eat Well and Keep Moving). He has been a faculty member at Harvard for 38 years, served on 64 dissertation committees, and twice served as chair of the HSPH faculty council.

d. **Study drug, biologic and/or device registration status:** N/A

4. **Study type:**
   a. **Study design and phase:** This study is designed as a group randomized trial, with measures collected pre and post intervention. Physical activity will be objectively measured via accelerometer, and snack and beverage consumption will be measured via observed plate waste.

5. **Participant selection, Recruitment and Consent Procedures:**
   a. **Inclusion Criteria:** Children ages 5-12 attending out of school time programs in Boston. Staff who direct out of school time programs in Boston (interviews, questionnaires and program assessments only).
   b. **Exclusion Criteria:** None
   c. **Recruitment Procedures:** Out of school time programs will be recruited for this assessment through verbal contact by study staff in the summer of 2010. Programs will be evaluated regarding physical activity and meal offerings, including any changes they may make. Study staff provide out of school time programs with educational information on different choices they could make and intervention sites will participate in learning collaboratives focused on implementing the intervention. Programs may be randomized to receive the intervention earlier (2010 school year) or later (2011 school year) if they are amenable. Programs will be selected as a convenience sample from among all afterschool programs in the city.

Child participants will be recruited in Fall 2010 in written form through the program they attend. Program and study staff will distribute consent letters to parents/guardians of children attending the program. These letters will be distributed to the person who picks up each child at the end of the program and addressed to the child’s parent/guardian. Letters will be distributed at least one week in advance of the first day of assessment conducted at the program site by study staff.

One staff member from each site who is responsible for directing out of school time programming will be recruited by study staff to answer questions about the priorities of the program and their experiences implementing nutrition and physical activity programming. One staff member from each site who is responsible for directing out of school time programming will be recruited by study staff to answer a program assessment on the practices and policies of the program; no individual names will be collected.
d. **Consent Procedures:** Child consent will be obtained from parents/guardians of children asked to participate in the study. Program staff will distribute consent letters to parents/guardians of children attending the out of school time program. These letters will be distributed to the person who picks up each child at the end of the program and addressed to the child's parent/guardian. Letters will be distributed at least one week in advance of the first day of assessment conducted at the program site by study staff. Consent forms will be distributed at least three times to children and parents. Assent will be obtained from the child participants whose parents consented. Assent procedures will begin on the first day of the assessment, when study staff are visiting the site for observation. At the beginning of the program, study staff will read through the assent form with each child individually. They will give each child a form to read along with if possible. Program staff will keep a checklist of children’s names to check off who has received assent forms. Assent will be solicited from each child only once for the entire assessment period. The procedure will continue throughout the week only to solicit assent from children who were not present earlier in the week.

Consent and assent will only be solicited for accelerometer and plate waste procedures and will not apply to observation procedures. Observation will be conducted at the site among the afterschool program group as a whole, and obtaining consent and assent for these procedures would disrupt the afterschool program more than not obtaining consent and assent for these observations. Refusal to consent or assent to observation procedures would result in denial of services for children through isolation from regular program activities.

Site director consent will be obtained from consent forms distributed by study staff during program visits.

6. **Study Procedures:**

a. **Research procedures/tests:** Study staff will visit program sites for one week each for assessment (both at baseline and follow up). Study staff will complete an observational tool on-site to assess the program’s nutrition and physical activity environment. Aside from being observed, children will be asked to do two things they would not normally be doing in their program. First, children will wear an accelerometer to measure daily physical activity. They will wear meters around the waist on an adjustable belt provided by study staff. Meters will be worn during program time for five week days, starting on Monday and ending on Friday. Children will be instructed only to remove meters during water activities (e.g. swimming). Second, children will leave behind uneaten snacks and beverages at snack time (i.e. "plate waste"). Study staff will measure the uneaten foods and beverages to assess how much food was eaten during the program by the children, after collecting information on the food being offered each day. We will also collect organization level data, such as policy documents, self-assessments of the nutrition and physical activity environment, and daily snack menus. Site director paper and pencil questionnaires and in-person interviews will be conducted to collect basic demographic information and to understand program priorities and experience implementing nutrition and physical activity programming. Interviews will be recorded and conducted.
by trained study staff. Study staff will conduct observations of meals offered, as well as activities students engage in during program time. Program staff will also be asked to complete a 5 day observation of the nutrition and physical activity offerings, as well as an assessment of written policies, at their program.

b. **Number of study visits, procedures and duration of each visit:** There will be 5 study observation visits at each program for baseline and follow up. Study staff will visit each program from Monday through Friday for one week. Study visits will last for the duration of the program, anticipated to be two to four hours. Accelerometer, plate waste, snack menu collection, and direct observation protocols will be done each day. Assessment of the physical space and environment will be done on one day. Policy documents, self-assessments, and other documents will be requested prior to study visits and collected by the end of the study visit week. Site directors’ questionnaires and interviews will also be conducted at baseline and follow up. The site director questionnaire is expected to take 10 minutes to complete and the interview will be approximately 20 minutes in duration. Program staff will also be asked to complete a 5 day observation of the nutrition and physical activity offerings, as well as an assessment of written policies, at their program at follow-up.

c. **How long will each participant be involved in the study:** Each participant will be involved in the study for at least one week at baseline and one week at follow up. Initial contact with parents/guardians will begin at least one week prior. Study staff may return to sites midway through the school year to conduct observational assessments. Site directors will be involved for 1 school year.

### 7. Foreseeable Risks and Potential Benefits:

a. **Risks/Discomforts/Inconveniences:** Participating in multi-day physical activity and nutrition monitoring protocols may be inconvenient to some individuals.

b. **How will risks/discomforts/inconveniences be minimized:** Accelerometers will be worn on an adjustable belt over clothes to minimize discomfort from wearing this device. Inconvenience will be minimized by the short one-week period of study (at baseline and at follow up).

c. **Expected benefits to participants, population, country and/or society:** The study will benefit youth-serving organizations and programs that have potential to promote healthy development through foods, beverages and physical activity. There may be broader benefits to society in preventing chronic disease related to improved nutrition and increased physical activity. There are no direct benefits intended for individuals.

### 8. Costs/Payments:

a. **Costs to participants:** There will be no additional costs to participants.

b. **Type of payment to participants:** Child participants will not be paid. Adult participants completing the self-assessments may be paid for their completion via gift cards for up to $25.

### 9. Safety Assessment:

a. **Adverse event (AE) reporting plan including frequency and who will be responsible:** The Principal Investigator will report any adverse events promptly.
10. Study Monitoring and Quality Assurance:
   a. Protocol adherence monitoring plan including data reviewed, frequency, and who will be responsible: The Principal Investigator will closely monitor data after data collection to ensure the information is collected according to protocol.

11. Privacy and Confidentiality:
   a. Methods used to protect the privacy of participants: Participants and their parent/guardian will be given the choice to participate in this study. Parents/guardians will provide consent, and children will provide assent. Site director’s written consent for interviews, questionnaires, and the 5-day observational assessment will be obtained from consent forms distributed by study staff during program visits.

   b. Methods used to protect the confidentiality of data collected: Individual data will be seen only by study staff. Summarized results at the level of the program group will be shared with program staff, but individual data will not be shared. No identifying information will be collected. Study staff will maintain a program roster in order to keep track of consent/assent. To ensure continuity of accelerometer wearing over time (i.e. the same child wears the same accelerometer for the entire one-week assessment period), accelerometer belts will be marked with masking tape. Each child’s first name will be written on a piece of masking tape and taped to the belt, and this belt will be given back to the child each day of the assessment. An arbitrary unique participant ID will be matched to the accelerometer number of the accelerometer worn by the participant, and analyses will be conducted using this participant ID as the unit of analysis. No names will be used.

12. Sending/Receiving Data Specimens to/from Research Collaborators Outside of HSPH: N/A