

**Targeted Surveillance and Biometric Study for Enhanced Evaluation of
Community Transformation Grants**

New

Supporting Statement

Part A—Justification

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PART A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) supporting a Targeted Surveillance and Biometric Study to collect key outcomes required by the Patient Protection and Affordable Care Act (ACA) in up to 20 selected awardee areas/geographic regions funded through the Community Transformation Grants (CTG) Program. The Centers for Disease Control and Prevention's (CDC's) authorization to conduct this study is provided by the Public Health Service Act (Attachment 1A). The Office of Management and Budget (OMB) approval is being requested for the first three years of a six-year project. CDC plans to seek an extension of OMB approval to support continued data collection through the final three years of the six-year CTG Program award period. From the ACA mandate, CDC established the CTG Program and funded awardees to create healthier communities through implementation of policy, environmental, programmatic, and as appropriate infrastructure changes needed to promote healthy living and reduce disparities. Evaluation of the CTG Program is mandated as part of the ACA (Attachment 1B):

The Secretary of Health and Human Services, acting through the Director of the CDC shall award competitive grants to State and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming. [ACA Section 4201]

The ACA further specifies that measures for the following core outcomes must be collected and assessed over time:

- i. changes in weight;
- ii. changes in proper nutrition;
- iii. changes in physical activity;
- iv. changes in tobacco use prevalence;
- v. changes in emotional well-being and overall mental health; and
- vi. other factors using community-specific data from the Behavioral Risk Factor Surveillance Survey; and
- vii. other factors as determined by the Secretary.

In addition to the five core outcome measures cited in the ACA above (items i-v), the Department of Health and Human Services (HHS) determined that an assessment of objective changes in body mass index (BMI) should be performed (per item vii). CDC developed an evaluation plan to align with the mandates of the ACA and the resulting CTG Program. Although there are multiple components of the evaluation plan, this ICR requests approval for a Targeted Surveillance and Biometric Study. This current ICR complements two additional requests that OMB has approved: Monitoring and Reporting System for CTG Awardees (OMB No. 0920-0946, exp. 8/31/2015) and Use of System Dynamics Modeling and Economic Analysis in Select Communities (OMB No. 0920-0937, exp. 6/30/2015). Separate requests will be submitted to OMB for related evaluation studies that require data collection.

In fiscal year 2011, \$102.6 million was authorized for the CTG Program (CDC-RFA-DP11-1103PPHF11) to fund state and local governmental agencies, tribes and territories, state or local nonprofit organizations, and national networks of community-based organizations. The purpose of this funding is to implement, evaluate, and disseminate evidence-based community preventive health activities to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence base for effective prevention programming. Section 4201 of the ACA specifies that an evaluation of CTG is to be conducted “to measure changes in the prevalence of chronic disease risk factors among community members participating in preventive health activities.” In implementing this mandate, CDC designed a multicomponent national evaluation of CTG that includes this Targeted Surveillance and Biometric Study for Enhanced Evaluation of the CTG Program described within this ICR. This study is a population-based household assessment of persons three years of age and older who live in 20 CTG awardee areas that are currently implementing interventions. Adults in selected households will be asked to complete an Adult Targeted Surveillance Survey (ATSS) as part of a *Standard Protocol* of data collection. In addition, to meet the HHS request for an assessment of changes in BMI, a subsample of households of participants from 8 of the 20 participating awardee areas will be selected to participate in an *Enhanced Protocol* of data collection. Because we are assessing outcomes across a broad range of ages, and to use resources optimally, we have designed different data collection methods based on participants’ age and whether they will be invited to participate in the *Enhanced Protocol*. All participants, regardless of age, will be administered a questionnaire (either by telephone or in person) that assesses the same outcomes (i.e., as specified in the ACA).

As described above, outcomes specific to each of the five strategic directives are to be collected and assessed over time through targeted surveillance and special and enhanced evaluation studies (Attachment 4A): (1) tobacco-free living; (2) active lifestyles and healthy eating; (3) high-impact, evidence-based clinical and other preventive services; (4) social and emotional well-being; and (5) healthy and safe physical environments. The CTG Program awardees will create healthier communities through implementation of sustainable, evidence- and practice-based jurisdiction-wide strategies in counties, states, tribes, and territories. The following provides a rationale supporting the proposed data collection for each of the five strategic directives:

1. Tobacco-free Living

Tobacco use is the leading cause of preventable death and disability in the United States. Each year, tobacco use is responsible for approximately 443,000 deaths, an estimated 49,000 of which are the result of secondhand smoke exposure.¹ Nearly one in five adults (19.3%) is a current smoker,² and 40.1% of nonsmokers are exposed to secondhand smoke.³ Despite overall declines in tobacco use over the past several years, disparities in smoking prevalence persist among all sociodemographic groups. Promising strategies to reduce smoking prevalence and exposure to secondhand smoke include increasing the cost of tobacco products, adopting and implementing smoke-free environmental changes, and implementing anti-tobacco educational efforts, among other jurisdiction-wide strategies.⁴ However, there are several gaps in the evidence for how these efforts may work independently or in tandem to effect positive change in key tobacco-related outcomes.^{5,6} Further, current public health surveillance systems are limited in their capacity to link exposure to promising strategies with biometric measures of smoking and

secondhand smoke exposure, such as enzyme immunoassays to measure cotinine. Cotinine is a validated measure of exposure to smoking⁷ that has been considered the “gold standard” to evaluate the effectiveness of smoke-free policies.⁸

2. Active Lifestyles and Healthy Eating

In the United States, about 34% of adults and 17% of youth aged 2–19 are considered obese.^{9,10} Obesity contributes to chronic health conditions such as heart disease, stroke, type 2 diabetes, and certain types of cancer, which are some of the leading causes of death.² Obese persons also place a large financial burden on our medical care system because their care tends to be more costly.² Although obesity is a growing problem across the entire United States, certain populations are disproportionately affected: non-Hispanic black women and Hispanics have the highest rates of obesity (41.9% and 30.7%).¹¹ Communities characterized by lower income, less education, and more blue-collar workers also tend to have higher rates of obesity.¹²

The two most important individual behaviors associated with maintaining a healthy weight are living an active lifestyle and eating a healthy diet, yet very few Americans are achieving the current recommendations.² A number of factors have contributed to the obesity epidemic, including community barriers to physical activity and increased access to and availability of unhealthy foods and beverages. Populations with the highest rates of obesity tend to have less access to fresh fruits and vegetables or to safe places for physical activity.²

Specific to physical activity, HHS released the first official government physical activity guidelines in 2008, recommending at least 150 minutes per week of moderate intensity aerobic activity, 75 minutes per week of vigorous intensity aerobic activity, or a combination of the two. It is important to measure multiple dimensions of physical activity contributing to the guidelines, including both the duration of aerobic activity and intensity of these activities.¹³

Increasingly, sedentary time (too much sitting) is being recognized as a distinct health risk behavior.¹⁴ A recent review of the literature pertaining to this risk factor recommends that, wherever possible, population-based monitoring of sedentary time incorporate both self-reported measures (to capture important domain- and behavior-specific sedentary time information) and device-based measures (to measure both total sedentary time and patterns of sedentary time accumulation).¹⁵ The study described in this ICR includes both types of measurements.

3. High-impact, Evidence-based Clinical and Other Community-based Preventive Services

Access to clinical and community preventive services can prevent or control high blood pressure and high cholesterol levels through early detection and clinical management. High blood pressure and high cholesterol levels are known contributors to the leading cause of death in the United States.² Cardiovascular disease (CVD) kills more than 800,000 adults in the United States each year, and of these, 150,000 are younger than age 65.² National experts agree on a set of recommended clinical preventive services that can help detect and delay the onset of CVD. Despite the importance of screenings in

preventing CVD, only one in four Americans aged 50–64 is estimated to be up to date in receiving these services. This rate has remained virtually unchanged since 2002.¹⁶

Periodic screenings allow for the early detection and treatment of both high cholesterol and hypertension; however, disparities in screenings exist between sociodemographic groups. Adults aged 45–64 with low income are 15% less likely than their high-income counterparts to have received cholesterol screening in the past five years. Adults with low income are also 30% less likely than adults with high income to have controlled blood pressure. Hypertension is also more prevalent among blacks and American Indians than among whites.¹⁶ There are still gaps to be filled with regard to ensuring access to appropriate preventive services. Research is needed to link systems changes and jurisdiction-wide strategies, such as establishment of health information technology systems in physician offices, or a heavier reliance on pharmacists to manage multiple medications, with improved access to clinical care.

4. Social and Emotional Well-being

Research has shown that mental illness is associated with increased risk for chronic medical diseases. In 2004, an estimated 25% of adults in the United States reported having a mental illness in the previous year.² Researchers have estimated that approximately 50% of U.S. adults will develop at least one mental illness during their lifetime and that, as of 2002, the economic burden was more than \$300 billion.² Racial and ethnic health disparities have been observed in the treatment of adults for serious mental illness, depression, and schizophrenia. White non-Hispanic adults aged 18 years or older with serious mental illness had the highest (best) rate of treatment, 68% in 2002, whereas Hispanic or Latino and black non-Hispanic adults with serious mental illness had treatment rates of 45% and 51% in 2002, respectively.¹⁷ Research suggests that there is a correlation between social and emotional well-being and healthy living among children and adults, such that higher levels of well-being are associated with decreased risk of disease, illness, and injury; better immune functioning; higher work productivity; speedier recovery; and increased longevity.⁴ However, these findings are from individual studies, and currently there are no surveillance efforts such as the CTG Program's proposed Targeted Surveillance and Biometric Study to assess these issues.²

5. Healthy and Safe Physical Environments

Studies have shown that regular physical activity is associated with improved overall health and fitness and reduces the risk for many chronic diseases.¹⁸ The 2008 Physical Activity Guidelines Advisory Committee notes that data from various national surveillance programs consistently show that most adults and youth in the United States do not meet current physical activity recommendations (e.g., 45% to 50% of adults and 35.8% of high school students say they get the recommended amounts of moderate to vigorous physical activity).¹⁹ This is an improvement over the last decade, when only 25% of adults in the United States reported engaging in recommended levels of physical activity (i.e., either 30 minutes of moderate-intensity activity on ≥ 5 days/week or 20 minutes of vigorous-intensity physical activity on ≥ 3 days/week), and only 27% of grade 9–12 students received moderate-intensity physical activity.¹⁸ However, disparities persist in the United States with respect to rates of chronic disease and physical activity

levels.^{20,21} This may be associated with a lack of healthy and safe physical environments in which to be physically active.

Environmental and policy approaches are designed to provide opportunities, support, and cues to help people be more physically active.²² There is a growing body of evidence that supports such approaches, which benefit all persons exposed to the environment, rather than approaches focusing on changing physical activity at the individual level.²³ The environmental and policy approaches hold particular promise for promoting physical activity and should be taken into account when designing physical activity interventions.²³ Other promising strategies to increase physical activity include implementing design and land use policies and practices that support physical activity in urban areas and creating or enhancing access to places for physical activity.^{22,24}

Design and Evaluation of the CTG Program to Address the Five Strategic Directives

The goals of the CTG evaluation plan (Attachment 4B) are to (1) conduct strategic and rigorous evaluations in collaboration with awardees to fill critical gaps in the evidence base; (2) acknowledge and understand the complex and dynamic environments in which we work, live, learn, play, and pray; (3) address questions related to health disparities and health equity; and (4) assess change in variables related to the five strategic directives, as specified in the ACA legislation. As previously described, even though there are multiple components of the CTG evaluation plan, this ICR requests approval for a Targeted Surveillance and Biometric Study (depicted in Exhibit A.1.1) that includes the collection of behavioral and biometric measures from adults and youth (aged three years and older) using a household approach that includes the following:

- *Standard Protocol:* A population-based assessment of adults aged 18 and older sampled from households in 20 selected CTG awardee areas (Attachment 4C) where interventions are being implemented that address the aforementioned Strategic Directives. Data will be collected from adults via the ATSS.
- *Enhanced Protocol:* An in-home visit to collect biometric measures in a subsample of adults and youth from households in 8 of the 20 CTG awardee areas selected for the *Standard Protocol*. Participants in the *Enhanced Protocol* will provide additional data, including adult and youth biometric assessments; a Youth Survey completed by selected children (if aged 12–17 years); or a Caregiver Survey completed by a parent or an identified caregiver (if selected child is aged 3–11 years). Without the *Enhanced Protocol*, CDC would not have any information on children or objective biometric data on any respondent to fulfill critical gaps in the evidence base.

The Specific Aims of the proposed study are the following:

1. Analyze trends in behavioral and biometric indicators of risk factors for chronic disease, with priority given to assessment of weight, diet, physical activity, tobacco use, and exposure to secondhand smoke in children and adults in CTG awardee areas. Data collection activities addressing Specific Aim 1 will include the following:
 - a. *Standard Protocol:* Conduct the ATSS biennially in a representative sample of adult residents living in geographic areas targeted for interventions by 20 CTG Program

awardees (starting in 2013 pending OMB approval, 2015, and in 2017 pending OMB renewal). The same instruments and sampling designs will be used for each period of the ATSS administration.

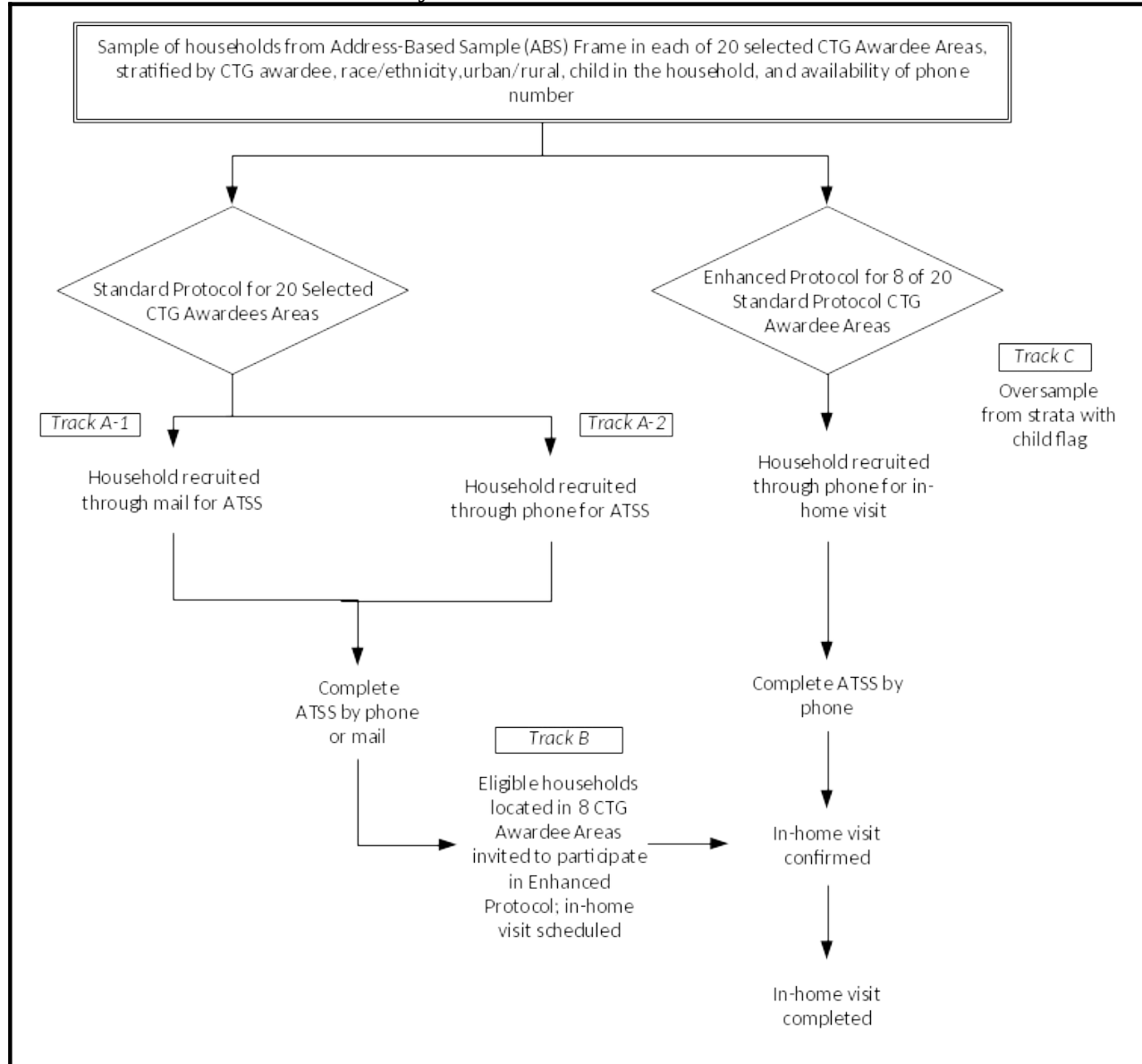
- b. *Enhanced Protocol*: Obtain biometric measurements for adults and youth, and conduct youth/caregiver interviews in a subsample of ATSS households in the same geographic areas targeted by 8 of the 20 CTG Program awardees involved in the *Standard Protocol*.
2. Assess the reduction in disparities in high-interest health indicators within special populations in CTG awardee areas. Data collection activities addressing Specific Aim 2 will include the following:
 - a. Oversample respondents for the *Standard Protocol* from African American, Hispanic, and rural populations to allow for estimation of changes in high-interest indicators within these groups.
 3. Explore the ways in which individual health is linked to community environmental factors that affect how people live, work, learn, pray, and play. Data collection activities addressing Specific Aim 3 will include the following:
 - a. Collect behavioral and biometric information on adults and adult-child pairs selected from the *Enhanced Protocol* subsample to be evaluated in relation to community contextual information and indicators of CTG Program activities.

Privacy Impact Assessment Information Overview of Data Collection System

The CTG Targeted Surveillance and Biometric Study will include data collection from adults using a *Standard Protocol*, as well as biometric and behavioral data from a subsample of adults and children residing in the same household as participating adults using an *Enhanced Protocol*. Exhibit A.1.1 provides an overview of the data collection flow for the two protocols. In the exhibit, we refer to four possible tracks of data collection a respondent can follow through the study (detailed description provided in Section B.2) including:

- Tracks A-1 and A-2—Selection of household in all 20 CTG awardee areas for inclusion in the *Standard Protocol* with initial data collection through mail (Track A-1) or telephone (Track A-2).
- Track B—Invitation to households in the eight CTG awardee areas selected for the *Enhanced Protocol* to participate in this protocol, which involves an in-home visit by a trained field interviewer.
- Track C—Oversample of households with “child flags” (i.e., the presence of at least one child aged 3-17) in the eight CTG awardee areas and obtain their consent by telephone to participate in both the *Standard Protocol* and *Enhanced Protocol*.

Exhibit A.1.1. Overview of the *Standard* and *Enhanced* Protocols of the Targeted Surveillance and Biometric Study



Standard Protocol

As shown in Exhibit A.1.1, data will be collected using the ATSS from adults in specific geographic areas where 20 CTG awardees are implementing interventions. This *Standard Protocol* (depicted on the left side of the exhibit) will involve mailing the ATSS to a sample of adults residing in households in these selected areas (Track A-1 in exhibit), or calling a portion of the sample to recruit them for the study (Track A-2 in exhibit). The paper-based version of the ATSS that will be distributed to respondents via mail is labeled “CTG Program Evaluation Survey Booklet.” Respondents will also have the option of calling a toll-free number to complete the ATSS. The ATSS is an address-based, multimode survey that will be conducted biennially, with data collection periods starting in 2013 (pending approval by OMB), 2015, and 2017 (pending renewal by OMB).

This data collection for the *Standard Protocol* uses a quasi-experimental design to assess the impact of adoption and implementation of CTG activities on intermediate, long-term, and ultimate health-related outcomes by conducting repeated cross-sectional surveys in randomly selected households in geographic areas targeted for interventions by 20 awardees. Questions will focus on assessing respondents' own beliefs and behaviors related to the five strategic directives for the CTG Program (Section A.1). The ATSS has been designed using items from existing national and state data systems such as the state-based Behavioral Risk Factor Surveillance System (BRFSS).²⁵ A list of data sources reviewed for relevant items to be included in the ATSS can be found in Attachment 5. Data from the ATSS will be compared with existing data from the BRFSS for the county or state in which the area is located as well as estimates from other existing state and national surveillance systems, where available.

Enhanced Protocol

Households in the eight CTG awardee areas selected for the *Enhanced Protocol* will have two mechanisms through which they can participate in this additional data collection. They can either be among the households selected initially for the *Standard Protocol* (i.e., Track B) such that once the adult completes the ATSS and is determined to reside in an eligible household, he or she will be invited to participate in the *Enhanced Protocol* or be among those in an oversample of households with a "child flag" from the sampling frame (i.e., Track C, see Exhibit A.1.1).

Both adults and children (aged 3–17 years) who are recruited through Tracks B or C will be invited to participate in the *Enhanced Protocol* and both adults and children will provide biometric measurements as part of their participation. These biometric measurements are designed to yield data to comply with an HHS request for an objective assessment of changes in BMI and to obtain data from and about children residing in each location. Both the collection of biometric data and the inclusion of children in the *Enhanced Protocol* will help to fill data gaps in existing surveillance systems.

Data collection for the *Enhanced Protocol* will therefore include the following methods, in addition to the completion of the ATSS by one adult in the household:

- a. In households with an eligible child, an interviewer will administer either a Youth Survey to children aged 12–17 to obtain self-reported information on diet, physical activity, and tobacco use or exposure, or a Caregiver Survey to the parent/caregiver for children aged 3–11.
- b. Biometric data will be collected from a selected child, if any child in that household is participating, and from the adult who completed the ATSS.
- c. In a subset of households with eligible children who participate in the *Enhanced Protocol*, data on physical activity will be collected by having the adult and selected child wear activity monitors (accelerometers) during waking hours for seven days. Additionally, participants wearing the monitors (or their caregivers, for children aged 3–11) will complete an "Activity Diary" to record the time they got up in the morning and went to bed at night on each of the seven days of monitoring, and the time and reason the activity monitor was removed for five minutes or more.

Only one child per household will be selected for the *Enhanced Protocol* involving the survey and biometric measures; only a subset of these will participate in the accelerometer and activity diary data collection.

Data collection for the *Standard Protocol* (using the ATSS) will be completed either by a trained telephone interviewer (TI) via computer-assisted telephone interviewing (CATI) or by the respondent him- or herself via a paper instrument. All additional data collection for the *Enhanced Protocol* will be conducted in the respondent's home by a trained field interviewer (FI) using computer-assisted personal interviewing (CAPI), whereby the interviewer uses a computer to read questions and enter respondents' answers. The FIs will also be trained to collect all of the biometric data from both adults and youths (see Section B.2 for additional details). In four of the eight awardee areas where the *Enhanced Protocol* will be conducted, selected household participants will also be asked to wear accelerometers and trained in their use by the FI. If they agree, both the adult and child participating in the accelerometry data collection will complete an Activity Diary over a seven-day period in which they are wearing the accelerometer (a caregiver will complete the diary for children aged 3–11). The FI will leave the accelerometer with the respondents with instructions (and a stamped, self-addressed envelope) on how to return the completed Activity Diaries (for adult and child) and accelerometers for processing.

Items of Information to Be Collected

Exhibit A.1.2 provides a summary of the content of the data collection instruments to be administered through this study and specifies the sample sizes for each. The topics to be addressed by the various data collection instruments are described subsequently.

Standard Protocol: Adult Targeted Surveillance Survey

The items of information to be collected focus on the following areas: sociodemographic characteristics; physical activity; indicators of proper nutrition such as fruit and vegetable intake; cigarette smoking; high blood pressure and treatment of the condition; high cholesterol and treatment of the condition; emotional and general well-being; and awareness, knowledge, and beliefs about risk factors related to obesity and chronic diseases (Attachment 7A).

Questions on the survey were selected to avoid topics that might be sensitive in nature (e.g., questions that might be embarrassing, be very private, or involve illegal behavior). Items have been drawn from existing data sources with valid measures, including the state-based BRFSS²⁶ and the National Health and Nutrition Examination Survey (NHANES).²⁷ New items were developed to facilitate participant selection and interpretation of biometric measurements (Attachment 7D identifies the source for all items on the survey).

Enhanced Protocol: Youth and Adult Biometric Measures

Data collection will be conducted in a subsample of households in which an adult was selected to first complete the *Standard Protocol* (i.e., ATSS) and has also consented to a home visit. Households with children will be oversampled to ensure that an adequate number of child biometric measures and surveys are obtained. If the household has more than one child, only one is selected to participate in this protocol through a process described in Section B.2.

The data collected through the *Enhanced Protocol* focus on the following areas: quantitative biometric measures from adults and children; health behavior data from or about children; and objective physical activity data.

- a. **Quantitative Biometric Measures.** The proposed biometric measures to be collected are noninvasive and produce no discernible risk to participants. Proposed measures include the following:
 1. **Anthropometry:** BMI, measured as weight in kilograms divided by height in meters squared (Kg/M^2), and waist circumference (centimeters) are both objective measures of obesity. These indices will quantify levels of obesity and are related to dietary habits and physical activity. BMI and waist circumference are also predictors of chronic disease (diabetes, CVD) in adults and in children and adolescents. Decrease in obesity prevalence is one of the primary goals of the CTG Program.
 2. **Saliva Cotinine:** Saliva cotinine determinations provide an objective, biologically relevant measure of exposure to secondhand smoke in children and adults and tobacco use in adults. The impact of CTG activities on tobacco use and secondhand smoke exposure can be assessed by comparing average cotinine levels prior to initiation of CTG activities with average levels after implementation.
 3. **Blood Pressure:** Data on systolic and diastolic blood pressure will be collected from adult participants only during the in-home visit. Resting heart rate will also be measured on adult participants. As described subsequently, these measures will be used to ascertain hypertension and current treatment of hypertension.
 4. **Other:** The FI will ask a short list of survey items to each adult and child providing biometric measures. The survey items for children are included as part of the Caregiver and Youth Surveys (Attachments 9A and 9B). The survey items for adults are included as part of the Adult Biometric Measures (Attachment 12A; Attachment 12C identifies the source for all items that precede the adult biometric measures). The survey items are all relevant to interpreting the collected data such as exposure to household smoking, how recently adult participants smoked or were around someone who was smoking, recent weight loss/gain, and the date and time of day of data collection. We expect, for example, that decreases in household smoking will be correlated with lower saliva cotinine levels. Adults with doctor-diagnosed hypertension or high cholesterol will be asked to provide details specific to their actions in controlling these conditions (e.g., use of antihypertensive or cholesterol-lowering medications, reduced salt intake).
- b. **Health Behavior Data.** For children participating in the *Enhanced Protocol*, the following additional data collection will be conducted (adults in the *Enhanced Protocol* will have already provided this information either by mail or over the telephone by completing the ATSS):
 1. **Caregiver Survey (Attachment 9A):** In-person survey data on children aged 3–11 years administered to an identified caregiver of the selected child through a CAPI-programmed instrument. When the child selected is 3–11 years of age, a parent/caregiver of the child living in the household will be asked to respond to the Caregiver Survey, which includes questions about the selected child’s eating and exercise behaviors, and exposure to secondhand smoke.

2. Youth Survey (Attachment 9B): In-person self-reported survey data on children aged 12–17 administered through a CAPI-programmed instrument. Questions will include assessment of the frequency of consumption of sugar-sweetened drinks including fruit juice, foods with high sugar and fat content, and consumption of healthy foods such as fresh vegetables. In addition, data specific to the setting in which physical activity occurs (e.g., leisure, transportation), and use of tobacco and exposure to secondhand smoke will be collected.

Questions on the Youth and Caregiver Surveys were primarily drawn from validated surveys or questionnaires. New items were developed to facilitate participant selection and interpretation of biometric measurements (Attachment 9C identifies the source for all items on the surveys).

- c. **Objective Physical Activity Data.** A subsample of *Enhanced Protocol* households will be selected for objective assessment of physical activity using an accelerometer. Seven days of accelerometer and associated Activity Diary data will be collected for one child (aged 3–17) and one adult from each selected household to calculate time spent engaging in physical activity and intensity of that activity. The accelerometer data will enhance our understanding of the levels of activity of individuals and relationships of that activity with levels at the community level for selected awardees in assessing the effects of CTG activities on increasing physical activity levels in children and adults, as well as estimating the extent to which members of the same household are similarly affected by CTG activities.

Exhibit A.1.2 provides an overview of the data collection instruments to be used for both the *Standard* and *Enhanced Protocols*, including the sample size goals, domains covered in each instrument, and the data collection mode.

Identification of Website(s) and Website Content Directed at Children Younger Than 13 Years of Age

This ICR does not refer children younger than 13 years of age to websites.

Exhibit A.1.2. Instruments for the Targeted Surveillance and Biometric Study

Protocol	Form Name and Description	Sampling Frame	Domains	Data Collection Mode
<i>Standard</i>	<u>Adult Targeted Surveillance Survey</u> —to obtain household surveillance data on the adults themselves and their household behaviors	Households within 20 awardee areas selected for their geographic and population diversity, oversampling for households likely to have blacks, Hispanics, or rural residents	Risk behaviors of the responding adult Risk behaviors of the household (e.g., how often they eat out, what types of foods they purchase, how often, how close is grocery store) Sociodemographics Willingness to participate in biometric data collection	CATI, paper

Protocol	Form Name and Description	Sampling Frame	Domains	Data Collection Mode
<i>Enhanced</i>	<u>Adult Biometric Measures</u> —to collect information specific to the biometric measures	Eight awardee areas of the 20 selected for the <i>Standard Protocol</i> ; adults who have completed ATSS either through Track B or C	Collection of height, weight, waist circumference, saliva, and blood pressure	In-home visit —CAPI instrument administered by field interviewer
	<u>Youth Biometric Measures</u> —to collect information specific to the biometric measures	Eight awardee areas of the 20 selected for the <i>Standard Protocol</i> ; children aged 3–17 years living in households with adults who completed ATSS	Collection of height, weight, waist circumference, saliva	In-home visit —CAPI instrument administered by field interviewer
	<u>Youth or Caregiver Survey</u> —to collect child-specific information on related behaviors (administered to youth aged 12–17; to caregiver for children aged 3–11)	Eight awardee areas of the 20 selected for the <i>Standard Protocol</i> ; children aged 3–17 years living in households with adults who completed ATSS	Physical activity Nutrition Smoking (children aged 3–11 are asked about exposure to secondhand smoke) Health and health care access Demographics Questions specific to the biometric data to be collected including exposure to secondhand smoke recent weight loss/gain	In-home visit —CAPI instrument administered by field interviewer
	<u>Activity Diary</u> (adults and youth aged 12–17 will complete diary themselves; caregiver/ parent will complete diary on behalf of child aged 3–11)	Four awardees, subsample of households completing <i>Enhanced Protocol</i>	Questions to help interpret the objective physical activity data Time got up in the morning and went to bed at night Time and reason the monitor was removed Type of activity and setting (transportation, leisure)	In-home visit, paper instrument completed by participant or caregiver; respondent wears accelerometer

CAPI = computer-assisted personal interviewing; CATI = computer-assisted telephone interviewing.

A.2 Purposes and Use of the Information Collection

The primary purpose of the CTG Targeted Surveillance and Biometric Study is to collect data to examine the extent to which CTG awardees achieve targeted improvements in the outcomes noted in the ACA: (i) changes in weight; (ii) changes in proper nutrition; (iii) changes in physical activity; (iv) changes in tobacco use prevalence; (v) changes in emotional well-being and overall mental health; and (vi) other key behavioral, biometric, and health status indicators. The CTG Program is a new initiative with requirements to create healthier communities by addressing the primary risk factors associated with chronic diseases (e.g., proper nutrition, tobacco use) through implementation of sustainable, broad, evidence- and practice-based strategies in counties, states, tribes, and territories. The goals of the CTG evaluation plan are to (1) conduct strategic and rigorous evaluations in collaboration with awardees to fill critical gaps in the evidence base; (2) acknowledge and understand the complex and dynamic environments in which we work, live, learn, play, and pray; (3) address questions related to health disparities and health equity; and (4) assess change in core variables related to the five strategic directives, as specified in the ACA legislation.

The data collected from the *Standard* and *Enhanced Protocols* will be used in multiple ways. First, the biennial data collection schedule will enable monitoring of changes in intermediate and long-term outcomes of interventions for a subset of CTG awardees. Second, the data will be used to determine the extent of health disparities at baseline and monitor progress toward reducing health disparities over time in racial and ethnic groups served by the CTG awardees. Third, the data will provide a scientific basis to assist CDC and other governmental agencies in determining the need and direction of additional programs and serve as a model for potential future assessments.

Privacy Impact Assessment

As described in Section A.10.A, the CDC has determined that the Privacy Act applies to this study. The applicable System of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. The Act applies to this study because, in the course of collecting data, respondents' names, addresses, and telephone numbers will need to be stored in order to follow up with each respondent involved in the *Enhanced Protocol* data collection. As data are collected, they will be stored behind an Enhanced Security Network (ESN) that provides data security and availability at the National Institute of Standards and Technology (NIST) "Moderate" level. We have developed an Information System Security Plan based on NIST Special Publication 800-53 controls and other applicable standards to describe administrative, technical, and physical safeguards to protect the security and availability of the system and information collected for this project. All draft documentation has been provided to CDC's Information Systems Security Officer and an Authority to Operate has been temporarily granted by CDC. Section A.10 provides more details about the process of data collection and storage to maintain high security for respondent identities.

Once all data from a respondent have been collected, the file will be stripped of any personally identifiable information (PII) before being made available to analysts for processing. As data are analyzed, the findings will be provided to awardees of the surveyed areas with supporting documentation (e.g., methodology, data tables, data format, and data use instruction) and may be used in numerous community newsletters, flyers, reports, briefings to local government, and

publications in scientific journals. CDC can use these findings in its publications, websites, congressional briefings, national conferences, and scientific journals.

A.3 Use of Improved Information Technology and Burden Reduction

State-of-the-art information technology and data collection procedures will be used throughout the implementation of the study to minimize respondent burden, including thorough, intensive training of interviewers so they are familiar with the various scenarios they may encounter on the telephone or in the field (so that respondent time is used efficiently), use of computer-assisted survey administration either by telephone or in person, and inclusion of skip patterns in the questions to minimize respondent burden.

Trained TIs will collect ATSS data in the *Standard Protocol* using CATI, unless the respondent chooses to use a paper instrument received in the mail. CATI and paper approaches are the most appropriate methodologies for collecting these data.²⁸ The ATSS is designed to have multiple skip patterns so that respondents can skip entire sections of the instrument if the domain is not applicable to them—this greatly minimizes respondent burden because each is directed to only answer personally relevant questions. In this way, the use of CATI helps to keep respondent burden low by customizing and streamlining the flow of the questions to present only those items that are relevant to the respondent based on information collected previously. Completing the ATSS over the telephone also enhances opportunities to explain details about completing the *Enhanced Protocol* via an in-home visit to those respondents who are eligible to participate in the *Enhanced Protocol*.

In addition, trained FIs will gather biometric data and health behavior data, as part of the *Enhanced Protocol*. Health behavior data are collected through the Youth Survey (Attachment 9B) and Caregiver Survey (Attachment 9A). The questions in these surveys are designed to obtain the required information while keeping respondent burden to a minimum. During household visits, the FI will administer the Youth Survey (for children aged 12–17 years) or the Caregiver Survey (for children aged 3–11 years) on a laptop computer using CAPI methodology. The interviewer uses a computer to read questions and enter respondents' answers. The CAPI approach is deemed the most appropriate data collection methodology for interviewer-assisted in-person administration of a questionnaire.²⁸ The CAPI software has the same features and advantages as the CATI in reducing burden for the respondent and presenting the question text, response options, interviewer instructions, and interviewer probes. It implements skip patterns to rapidly direct the interviewer to the relevant sections of the interview for the particular respondent, thus lessening the respondent burden. It also performs range checks and other consistency checks during the interview to ensure high-quality data by automatically detecting errors or questionable data in real time.

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

In developing the measures and instruments for this study, a thorough review of the literature and available surveillance systems was conducted to ensure that the data collected through this effort are not duplicative of existing surveillance systems and respondent burden is minimized. In addition, the CDC Targeted Surveillance/Biometry (TS/BIO) study team worked closely with the National Heart, Lung and Blood Institute (NHLBI) Healthy Communities Study (HCS) team to ensure alignment between studies, in terms of having comparable instruments and data collection protocols, where possible. Although there are other existing surveillance systems that

measure several of the key outcomes for CTG (e.g., BRFSS and YRBSS),²⁹ these were not designed to allow estimation of trends at geographic levels being targeted by CTG awardees. The areas targeted by awardee interventions may occur across a range of geographies including the entire state; a single county, city, tribal area, or territory; or areas of the state excluding large counties (i.e., population of 500,000 or more). No single or combined set of existing surveillance systems is designed to provide population estimates for all high-priority indicators at all of these geographic levels, and the combination of multiple surveillance systems is limited by variation in indicator definitions or sampling approaches. In addition, existing surveillance systems do not include the population diversity in terms of age, race/ethnicity, and population density (with the greatest gap for middle-school-aged children and younger, nonwhite and Hispanic/Latino race and ethnic groups, and individuals living in rural areas). Finally, objective measurement of weight, blood pressure, physical activity and inactivity (in a subsample), and exposure to smoke is only done in an ongoing, standardized fashion at the national level as part of the NHANES or intermittently in select geographic areas such as the California Health Interview Survey.

Because the NHLBI HCS is being conducted concurrently with the TS/BIO study CDC's Division of Community and NHLBI worked together to provide additional comment here. Both agencies worked together to understand study purpose, methods and measure and aligned measures for demographics and key outcome variables related to child physical activity, nutrition and obesity. The HCS overlaps with the proposed TS/BIO study for a portion of the population (children ages 4 to 15) and one of five core outcomes (obesity). These studies are complimentary in terms of the broad research questions they are addressing and their study designs. The 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 CTG 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

No small businesses are involved as respondents to this data collection effort. These data collection efforts will involve only households of residents randomly selected from within CTG awardee areas.

A.6 Consequences of Collecting the Information Less Frequently

Data collection in the *Standard Protocol* will consist of the biennial administration of the ATSS in specific geographic areas where each of 20 selected CTG Program awardees are implementing interventions. Three cross-sectional, random samples of households will be recruited for measurement over a 12-month period starting in spring 2013 (within six weeks of OMB approval), spring 2015, and again in spring 2017 (upon renewal of OMB approval). If the information were collected on a less frequent basis, we would run the risk of missing changes in outcomes associated with particular CTG intervention approaches. With the exception of certain oversampled strata in certain awardee areas (e.g., African Americans), it is very unlikely that the same resident will be surveyed with the ATSS more than once over the years.

The *Enhanced Protocol* in-home data collection will be conducted in a subset of 8 of the 20 geographic areas targeted for the *Standard Protocol* and will follow the same biennial schedule. As with the *Standard Protocol*, if the information in the *Enhanced Protocol* were collected on a less frequent basis, we would run the risk of missing changes in outcomes associated with particular CTG intervention approaches. Given the size and population diversity of most of the geographic areas, it is very unlikely that the same household will be selected for an in-home visit more than once over three data collection periods.

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

This request fully complies with all guidelines of 5 CFR 1320.5. There are no special circumstances required.

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

A. A 60-day notice for public comments on the proposed data collection activities required by 5 CFR 1320.8(d) was published in the *Federal Register* on April 18, 2012 (Volume 77, Number 75, pages 23263-23264) (Attachment 2). No public comments were received.

B. RTI International consulted with CDC Subject Matter Experts and with persons inside and outside the study design team during development of the instruments to be used in this project. A list of experts who provided feedback for each instrument is provided in Exhibits A.8.1 and A.8.2.

Exhibit A.8.1. Subject Matter Experts at CDC Consulted for the Targeted Surveillance and Biometric Study

Name	Organization	Contact Information
Seraphine Pitt Barnes, PhD, MPH, CHES	Division of Population Health; National Center for Chronic Disease Prevention and Health Promotion	Phone: (770) 488-6115 Seraphine.pittbarnes@cdc.hhs.gov v

Name	Organization	Contact Information
	(NCCDPHP)	
Nilka Burrows, MPH	Division of Diabetes Translation; NCCDPHP	Phone: (770) 488-1057 nilka.burrows@cdc.hhs.gov
Dan Chapman, PhD	Division of Population Health; NCCDPHP	Phone: (770) 488-5463 daniel.chapman@cdc.hhs.gov
Pyone Cho, MD	Division of Diabetes Translation; NCCDPHP	Phone: (770) 488-2041 igz1@cdc.gov
Kristine Day, MPH	Division of Community Health; NCCDPHP	Phone: (770) 488-5446 kday@cdc.gov
Martha Engstrom, MS	Office of Smoking and Health; NCCDPHP	Phone: (770) 488-5749 martha.engstrom@cdc.hhs.gov
Charlotte Kent, PhD	Division of Community Health; NCCDPHP	Phone: (770) 488-6471 Cgk3@cdc.gov
Brian King, PhD	Office of Smoking and Health; NCCDPHP	Phone: (770) 488-5107 baking@cdc.gov
Rosemarie Kobau MPH	Office of Noncommunicable Diseases, Injury and Environmental Health	Phone: (770) 488-6087 Rosemarie.kobau@cdc.hhs.gov
Youlian Liao, MD, PhD	Division of Community Health; NCCDPHP	Phone: (770) 488-5299 Ycl1@cdc.gov
Fleetwood Loustalot, PhD	Division for Heart Disease and Stroke Prevention; NCCDPHP	Phone: (770) 488-5198 fleetwood.loustalot@cdc.hhs.gov
Louise Murphy, PhD	Division of Population Health; NCCDPHP	Phone: (770) 488-5102 louise.murphy@cdc.hhs.gov
Rashid Njai, PhD	Division of Community Health; NCCDPHP	Phone: (770) 588-5215 rnjai@cdc.gov
Tatiana Nwankwo, MS	Division of Health and Nutrition Examination Surveys National Center for Health Statistics (NCHS)	Phone: (301) 458-4813 bwt4@cdc.gov
Diane Orenstein, PhD	Division of Community Health; NCCDPHP	Phone: (770) 488-8003 Dro1@cdc.gov
Yechiam Ostchega, PhD, RN	Division of Health and Nutrition Examination Surveys; NCHS	Phone: (301) 458-4408 yxo1@cdc.gov
Paul Siegel, MD, MPH	Division of Community Health; NCCDPHP	Phone: (770) 488-5296 pzsiegel@cdc.gov
Robin Soler, PhD	Division of Community Health; NCCDPHP	Phone: (770) 488-5103 rsoler@cdc.gov
Matthew Zack, MD, MPH	Division of Population Health; NCCDPHP	Phone: (770) 488-5460 Matthew.zack@cdc.hhs.gov

Exhibit A.8.2. List of Individuals and Organizations Other Than Those at CDC Consulted by the Study Team

Name	Organization	Contact Information
Joanne Arsenault, PhD	RTI International	Phone: (919) 541-8065 jarsenault@rti.org

Name	Organization	Contact Information
Frank Chaloupka, PhD	University of Illinois at Chicago	Phone: (312) 413-2367 fjc@uic.edu
Mary E. Clementi	A10 Clinical Solutions, Inc.	Phone: (404) 791-6347 mclementi@a10clinical.com
Kevin Davis, MA	RTI International	Phone: (919) 541-5801 kcdavis@rti.org
Matthew Farrelly, PhD	RTI International	Phone: (919) 541-6852 mcf@rti.org
Carole Harris, PhD	ICF International	Phone: (404) 321-3232 Charris5@icfi.org
James Hersey, PhD	RTI International	Phone: (202) 728-2486 hersey@rti.org
Andrew Hyland, PhD	Roswell Park Cancer Institute	Phone: (716) 845-8391 Andrew.Hyland@RoswellPark.org
Cathy Lesesne, PhD	ICF International	Phone: (404) 321-3232 clesesne@icfi.org
Megan Lewis, PhD	RTI International	Phone: (919) 541-6000 melewis@rti.org
Leslie Lytle, PhD	University of Minnesota	Phone: (612) 624-1818 lalytle@umn.edu
James Nonnemaker, PhD	RTI International	Phone: (919) 541-7064 jnonnemaker@rti.org
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Carol Schmitt, PhD	RTI International	Phone: (202) 728-2046 cschmitt@rti.org

A.9 Explanation of Any Payment or Gift to Respondents

The Targeted Surveillance and Biometric Study will provide respondents with gifts commensurate with the time they spend participating in the study. These gifts are comparable to gifts provided to respondents in similar studies approved by OMB. Respondents completing the ATSS in the *Standard Protocol* will receive a gift of \$20 as a token of appreciation. The proposed gift amount for this study is based on a review of monetary gifts for other recent large-scale state and national surveys administered using CATI that have similar respondent burden.³⁰ Evidence from the survey research literature also suggests that increasing the amount of the gift may also have a positive effect on response rates. We have chosen a gift that is commonly used in other large-scale surveys of similar kind and length. Sampled households will also receive \$2 along with their initial invitation letter, as an additional gift to participate. Small prepaid gifts have been found to produce improvements in screener response rates.³¹

Adult participants completing the in-home biometric data collection in the *Enhanced Protocol* will receive a \$40 gift, and child participants will receive a \$10 gift as a token of appreciation. We anticipate that the measures collected during the in-home visit will take on average 30 minutes for adults, 40 minutes for children 12–17 years of age, and 20 minutes for children 3–11 years of age to complete, along with another 20 minutes for their caregiver (i.e., adult who may or may not have completed the ATSS) to complete the survey. An additional \$20 gift will be sent to adults and \$10 to children who participate in the accelerometer component of the *Enhanced Protocol* and provide at least 4 days of data in which the monitor is worn at least 10 hours following the NHANES accelerometry protocol.^{32,33} The gifts will be explained to potential participants during recruitment over the telephone and as part of the informed consent process at the home visit. Proposed gifts are based on both the age of the participant (child vs. adult) and the level of participation. The proposed gifts are slightly lower than for participants of the longer (5.9 hours) NHANES visit,²⁷ where a gift of \$70 is given to persons aged 16 and older, and \$30 is given to children 2–15 years of age. The gift is also lower than for the Children’s Health after the Storms (CHATS) Study (OMB No. 0920-0925, exp. 3/31/2015), in which the token of appreciation varied from \$75 to \$135 per household, with incremental tokens of appreciation, based on activity and burden, provided for each completed activity.^a

A.10 Assurance of Confidentiality Provided to Respondents

All procedures have been developed in accordance with federal, state, and local guidelines, to ensure that the rights of participants are protected and data are appropriately safeguarded. The RTI Institutional Review Board (IRB) reviewed and approved all instruments, informed consent materials, and data collection and management procedures. RTI’s IRB approval notices are included as Attachments 3A and 3B.

A. Privacy Act Determination. CDC has determined that the Privacy Act applies to this project. The applicable System of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

B. Safeguards. The RTI Call Center staff and staff at the company subcontracted to complete the in-home visits are trained in procedures for ensuring privacy of participant information. Participant data are primarily collected using the computerized data management system (CATI or CAPI) and stored electronically. Under the NIST Moderate security level, these data are housed behind an additional firewall to ensure that no breach of stored data can occur. Paper records of responses to the mailed ATSS contain case IDs but no personal identifiers. In publications, the individual identities of participants are not disclosed, and data are reported only in the aggregate.

Data Collection

Information will be collected and managed according to a written security plan coordinated by one of CDC’s Information Systems Security Officers and approved by CDC’s Office of the Chief Information Security Officer. The security plan includes management controls, operational controls, and technical controls. We have planned for data security and availability at the NIST “Moderate” level.

^a The Gulf Coast’s Children’s Study, part of CHATS, includes gifts for children <8 years of age (an activity or coloring book was provided), for children aged 8–12 years (\$20 cash was given to the parent on behalf of their child), and for children aged 13–17 (\$30 was given to the participating child).

The data collection and management systems (CATI, CAPI) provide a high level of security including features such as user authorization (i.e., requirement of username and password to access the system) and encryption of sensitive data.

As respondent information is entered at a workstation, it is stored in the database residing on a secure server. Audit logs from the data management system provide complete documentation for changes to the database. Backups of the database and processing reports are made daily.

For ATSS interviews completed over the telephone (CATI) or returned on paper in the mail, data will be entered and stored on a private RTI server, which is subject to the RTI Security standards and methods outlined in the project security plan. All awardee-specific summary statistics derived from data collected by CATI or on paper will be de-identified and stored in the central CTG data repository.

For the CAPI interviews conducted during the in-home visits in the *Enhanced Protocol*, information will be collected on laptops using procedures that incorporate both operational and technical controls. This storage system will include collection of consent electronically through a specialized software system that allows for storage of respondent signature on the consent document. Study data on field devices such as laptops will be encrypted to Federal Information Processing Standard (FIPS) 140-2 and are further protected in transit by Security Socket Layers (SSL).

Accelerometers will be returned in a prepaid envelope to RTI. No personal identifiers can be stored on the devices, and the file name is stored using a monitor ID that is linked to the participant ID using an internal linkage file that is kept on a secure server.

Data Storage and Management

All data will reside on secure network servers in two RTI data centers with daily backups.

RTI security professionals are experienced with all security documentation and processes necessary to obtain an Authority to Operate and with all applicable HHS, CDC, Federal Information Security Management Act, Health Insurance Portability and Accountability Act, NIST, and other federal policies and regulations that may apply. RTI project team members and security professionals will ensure that all CDC-related technical and security standards, processes, and procedures are followed.

C. Consent. Consent will be obtained from each participant in the *Standard Protocol* prior to administering the ATSS (Attachments 6A, 6B, 6A-S, 6B-S). For surveys conducted via telephone, the interviewer will read an informed consent “script” displayed by the survey program. The participant will then give his or her verbal consent to proceed with the survey. Paper consent forms will be included as part of the paper questionnaires. Completion of the paper questionnaire will be considered documentation of consent. Both the telephone consent script and the paper questionnaire consent document will include a comprehensive description/purpose of the study, statement emphasizing the voluntary nature of the study, duration of the survey, gifts, risks or benefits to participants, and confidentiality procedures. The consents will be available or read in either English or Spanish. The consent documents will also clearly state that participation in each component of the study is completely voluntary, and participants can discontinue the study and opt out of any part of the study without penalty at any

time. Documentation and proof of subject consent will be stored at RTI. All consent documents will follow the guidelines outlined by CDC's Office of Human Subjects Protection and ethical guidelines set forth by the state and federal governments.

Upon arriving at the home for administering the *Enhanced Protocol*, FIs will read a script to the respondents briefly describing what the visit entails (see Attachments 11C, 11D, 11E, and 11F, and 11C-S, 11D-S, 11E-S, and 11F-S). Then FIs will obtain informed consent and youth assent (for children aged 7–17) for all data collected at the in-home visits conducted in the *Enhanced Protocol* (Youth Survey, Caregiver Survey, Youth Biometric Measures, and Adult Biometric Measures—Attachments 6C, 6D, 6E, 6C-S, 6D-S, 6E-S). A copy of the written informed consent forms will be provided to the participant for review prior to the start of the home visit. The consent documents will include a description of the overall study and expected roles and responsibilities of the primary caregiver and child, risks and benefits to participants, and confidentiality procedures. The consents can be read by these individuals or be read to them in either English or Spanish. For the youth component, an assent form is read to the child (aged 7 or older), the child assent is obtained, and a copy of the signed document is provided to the parent. The consent documents will also clearly state that participation in each component of the study is completely voluntary, and participants can stop the study or opt out of any part of the study without penalty at any time. As described previously, consent will be obtained and stored electronically for the *Enhanced Protocol* respondents. Survey responses will be electronically transferred to RTI, and the saliva collection kits will be sent to the RTI Biorepository via FedEx by the FI. Documentation of subject consent will be stored at RTI. Consent documents with identifiable information will be kept separate from the data collection documents.

All consent documents will follow the guidelines outlined by CDC's Office of Human Subjects Protection and ethical guidelines set forth by the state and federal governments.

D. Nature of Response. Participation in the Targeted Surveillance and Biometric Study is voluntary.

Privacy Impact Assessment

As described above, the system that will be used to store data collected through the Targeted Surveillance and Biometric Study has been built to ensure a moderate level of security of PII of respondents. For this reason, the respondent can be ensured that no linkage of data elements will be possible between their responses and their PII.

A.11 Justification for Sensitive Questions

All questions and procedures have been reviewed for issues of sensitivity and safety by the IRB. The potential sensitivity of questions and procedures is an evaluation criterion in determining content of the survey. We have purposely excluded topics that are known to be sensitive or that might interfere with participation.

In the informed consent procedure, all persons are advised of the voluntary nature of their participation in the survey or any of its components. Some of the questions or visit components included in the adult and child surveys and biometric studies that are not explicitly listed here may be considered sensitive; therefore, each person is reminded that he or she can refuse to answer questions or undergo any parts of the visit that he or she considers objectionable.

Interview Data

The questions in the ATSS are generally not of a sensitive nature and are commonly found in surveys of health behavior. Therefore, the data collection will have little or no effect on the respondent's privacy or cause physical or emotional discomfort. Questions relating to race/ethnicity and income can be considered somewhat sensitive. However, these questions are important and are necessary to evaluate whether the CTG Program results in reduction in health disparities in racial and ethnic populations. Collection of income data will enable investigators to determine whether improvements in health status have occurred within certain segments of the community.

The instruments used will ask questions that are consistent with the risk factors that the CTG Program seeks to modify. Therefore, questions concerning the use of tobacco are only asked of children aged 12–17, while questions about exposure to secondhand smoke are asked for all children. For the children aged 12–17, sensitive tobacco questions appear on showcards so the child can provide a letter response that the parent cannot see rather than answer the item outright. Similar questions are asked in many national surveys of adults and youth (e.g., CDC's National Adult Tobacco Survey [NATS] and National Youth Tobacco Survey [NYTS]); however, existing survey samples are not designed to be sensitive or specific enough to detect the effect of the CTG Program, especially on racial and ethnic populations with excess disease burdens. These privacy safeguards are being implemented in recognition of the potentially sensitive nature of some questions in this information collection.

Biometric Data

All content of a sensitive nature in the visit is explicitly discussed in the informed consent documents (Attachments 6B, 6C, and 6E). Saliva will be collected in persons three years of age or older to measure the level of cotinine. This specimen is necessary to provide a measure of exposure to secondhand smoke in all participants to allow evaluation of the effect of the CTG Program on an objective measure of this risk factor.

A.12 Estimated Annualized Burden Hours and Cost to Respondents

OMB approval is requested for three years (2013-2015). Exhibit A.12.1 provides an annualized summary of two waves of information collection that are scheduled to occur during this period. The third wave of information collection is scheduled to occur in 2017. Burden estimates for the third wave of information collection will be presented in a separate Revision request.

Information for the Adult Targeted Surveillance Survey (ATSS) will be collected from all respondents who participate in the *Standard Protocol* or the *Enhanced Protocol*. The ATSS will be fielded in two modes: a telephone interview (Attachments 7C/7C-S) and a self-administered paper booklet (Attachments 7A/7A-S). Both modes of administration are offered in English or Spanish.

To meet recruitment goals for the ATSS Telephone Interview, we estimate that the ATSS Telephone Screener (pages 1–20 of Attachments 7C/7C-S) will be administered to 13,749 respondents per year. The ATSS Telephone Interview (pages 26–64 of Attachments 7C/7C-S) will be completed by 7,311 respondents per year. The total estimated burden per respondent is 2 minutes for the ATSS Telephone Screener and 28 minutes for the ATSS Telephone Interview.

We aim to collect an average of 8,485 responses per year for the self-administered ATSS Paper Booklet. The paper booklet will be mailed to selected respondents labeled as the "CTG Program

Evaluation Survey Booklet.” Respondents may complete the ATSS Paper Booklet in English or Spanish (Attachment 7A/7A-S). The total estimated burden per respondent for the ATSS Paper Booklet is 30 minutes.

All respondents in the eight *Enhanced Protocol* CTG awardee areas who complete the ATSS by telephone or sample members from the *Enhanced Protocol* oversample will complete a screener to recruit them to participate in the *Enhanced Protocol* and to determine their eligibility (Attachments 10A/10A-S). Households that receive the ATSS Paper Booklet by mail will also receive a recruitment flyer for the *Enhanced Protocol* (Attachments 10B/10B-S); *Enhanced Protocol* oversample members with no telephone match will receive a recruitment letter that invites participation to both the *Standard* and *Enhanced Protocols* (Attachments 10D/10D-S). Interested persons may call the toll-free number provided or provide a phone number on the form provided. Respondents who call the toll-free number or are contacted at the phone number provided will complete a variation of the Adult Biometric Measures Recruitment Screener (Attachments 10C/10C-S). We expect a total of 4,418 individuals per year will complete the Adult Biometric Measures Recruitment Screener. All versions of the screener are offered in English or Spanish. The estimated burden per respondent for the screener is 10 minutes.

Adult Biometric Measures data will be collected on approximately 2,667 adults per year. Respondents are given the option to complete the interview portion of the exam or receive instructions for measurements in English or Spanish (Attachments 12A/12A-S). The estimated burden per response for collection of the Adult Biometric Measures is 30 minutes.

Accelerometry data and an associated Adult Activity Diary will be collected in four of the eight *Enhanced Protocol* CTG awardee areas. Data will be collected during the first wave of data collection (2013) only. Adults will wear the accelerometer for a total of seven days and complete the Adult Activity Diary provided to them in English or Spanish (Attachments 13B/13B-S). In addition, approximately 100 adults per year will be responsible for completing a similar Youth Activity Diary (Attachments 13C/13C-S) on behalf of a young child (aged 3–11 years) in their household who also provides 7-day accelerometry data. The estimated burden for adults to complete the Adult or Youth Activity Diary is 20 minutes.

Approximately 960 adults per year will complete a Caregiver Survey on behalf of a young child (aged 3–11 years) in their household (Attachments 9A/9A-S). The total estimated burden to complete the Caregiver Survey is 20 minutes.

The Youth Survey (Attachments 9B/9B-S) will be administered in the home to about 640 youth participants aged 12–17 per year. The Youth Biometric Measures (Attachment 12B/12B-S) will be collected on about 1,600 children aged 3–17 years per year. English and Spanish versions of the information collection instruments are available. The estimated burden per youth respondent is 20 minutes for the Youth Survey and 20 minutes for the collection of the Youth Biometric Measures.

Approximately 67 older children (aged 12–17 years) per year will wear an accelerometer for a total of seven days and complete the Youth Activity Diary provided to them in English or Spanish (Attachments 13C/13C-S). The estimated burden for children aged 12–17 to complete the Youth Activity Diary is 20 minutes.

Exhibit A.12.1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Adults completing ATSS in <i>Standard</i> or <i>Enhanced Protocol</i>	Adult Targeted Surveillance Survey–Telephone Screener (pp. 1–20)	13,749	1	2/60	458
	Adult Targeted Surveillance Survey–Telephone Interview (pp. 26–64)	7,311	1	28/60	3,412
	Adult Targeted Surveillance Survey–Paper Booklet	8,485	1	30/60	4,243
Adults completing in-home visit in <i>Enhanced Protocol</i>	Adult Biometric Measures–Recruitment Screener	4,418	1	10/60	736
	Adult Biometric Measures	2,667	1	30/60	1,334
	Adult Activity Diary	167	1	20/60	56
	Youth Activity Diary	100	1	20/60	33
	Caregiver Survey	960	1	20/60	320
Children completing in-home visit in <i>Enhanced Protocol</i>	Youth Survey	640	1	20/60	213
	Youth Biometric Measures	1,600	1	20/60	533
	Youth Activity Diary	67	1	20/60	22
Total burden hours					11,360

The cost for adult and child respondents can be calculated in terms of their time in responding to the ATSS and to the surveys and screeners and the time needed to collect the biometric measures. Exhibit A.12.2 provides an annualized cost to respondents, where the estimated respondent burden hours have been multiplied by an estimated average hourly wage for the total United States, because the respondents are expected to span the entire country. The average hourly wage was determined from U.S. Department of Labor, Bureau of Labor Statistics (www.bls.gov/cew/ew10table6.pdf; “Table 6. Private industry by State, 2010 annual averages: Establishments, employment, and wages”) by dividing 2010 total U.S. weekly wages by 40 hours. The combined total estimated respondent burden cost for conducting the *Standard* and *Enhanced Protocols* annualized over the three-year study period is **\$236,519**.

Exhibit A.12.2. Estimated Annualized Cost to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden (in hours)	Average Hourly Wage	Total Cost (per year)
Adults completing ATSS in <i>Standard</i> or <i>Enhanced Protocol</i>	Adult Targeted Surveillance Survey–Telephone Screener (pp. 1–20)	13,749	1	458	\$22.33	\$10,227
	Adult Targeted Surveillance Survey–Telephone (pp. 26–64)	7,311	1	3,412	\$22.33	\$76,190
	Adult Targeted Surveillance Survey–Paper	8,485	1	4,243	\$22.33	\$94,746
Adults completing in-home visit in <i>Enhanced Protocol</i>	Adult Biometric Measures–Recruitment Screener	4,418	1	736	\$22.33	\$16,435
	Adult Biometric Measures	2,667	1	1,334	\$22.33	\$29,788

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden (in hours)	Average Hourly Wage	Total Cost (per year)
	Adult Activity Diary	167	1	56	\$22.33	\$1,250
	Youth Activity Diary	100	1	33	\$22.33	\$737
	Caregiver Survey	960	1	320	\$22.33	\$7,146
Children completing in-home visit in Enhanced Program	Youth Survey	640	1	213	\$0	\$0
	Youth Biometric Measures	1,600	1	533	\$0	\$0
	Youth Activity Diary	67	1	22	\$0	\$0
Total Annualized Cost						\$236,519

A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

No additional costs will be incurred by the respondents.

A.14 Annualized Cost to Federal Government

Two types of costs to the Government will be incurred: (1) external contracted data collection and analyses and (2) government personnel. RTI is the data collection and management contractor. Total external (contractor) cost to the federal government for conducting this program evaluation is \$14,993,597 for the three years of the project. The annualized external (contractor) cost of the Targeted Surveillance and Biometric Study is \$4,997,866 (see Exhibit A.14.1).

The government costs include personnel costs for federal staff involved in project oversight and development of this ICR; these efforts involve approximately 10% of a GS-13 public health analyst @\$97,000/year (\$9,700); 20% of a GS-13 scientist @\$97,000/year (\$19,400), and 15% of a GS-14 scientist @\$115,000 (\$17,250). The estimated annualized cost of federal personnel is \$46,350.

The total annualized cost to the federal government is \$5,044,216.

Exhibit A.14.1 Itemized Annual Cost to the Federal Government

CDC Staff Member	Annual Salary	% Allocation (Annualized)	Cost
GS-13	\$97,000	10%	\$9,700
GS-13	\$97,000	20%	\$19,400
GS-14	\$115,000	15%	\$17,250
		Subtotal, CDC Personnel	\$46,350
Contractual Costs for Data Collection and Management (RTI)		Subtotal, Contractual Costs	\$4,997,866
		Total	\$5,044,216

A.15 Explanation for Program Changes or Adjustments

This is a new ICR supporting evaluation of a new programmatic initiative.

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

The Targeted Surveillance and Biometric Study consists of three repeated cross-sectional samples collected biennially in each of 20 awardees. RTI staff will create data sets that can be used in analyses within three months of completion of data collection for each measurement occasion. The process for preparing the data for analysis involves completing:

- an assessment of nonresponse bias (i.e., which determines the ability of results to be generalized to the target population);
- a final assessment of data quality including checking for item completeness, accuracy, and plausibility (with respect to compatibility with other data collected for the individual, validity checks, and comparison of summary statistics with expected distributions), as well as instituting corrective action (e.g., imputing for missing data, setting impossible values to missing);
- an assessment of the appropriateness of post-survey adjustment for sampling bias (see Section B.1); and
- calculation of sampling weights.

Prior to producing analyses for tabulations or publication, two teams of senior staff within RTI (Integrated Analysis and Cross-Evaluation Team, Dissemination Team) will review a standardized concept proposal that outlines the purpose and analysis plans for the tabulation or publication (including specification of key variables/outcomes, analytic methods, and proposed table shells/graphics). Assigned statistical and scientific reviewers will ensure that the purpose of the tabulation or publication are clearly stated and align with overall goals of the CTG Program evaluation and make sure that outcomes are consistently defined, and analysis guidelines applied (e.g., ensuring minimum sample size for subgroup analyses, consistent methods for handling missing data are used). Draft tabulations, graphs, and accompanied text will be provided to the CDC Division of Community Health Evaluation Lead for review. Following approval or clearance of tabulations or publications, they will be shared with stakeholders, presented at lay or scientific meetings, or submitted for publication in peer-reviewed journals.

Publications will fall into three broad categories: (1) papers documenting the key design elements of the study; (2) data-driven papers from Year 1 data collection that provide CTG Program planners and stakeholders with baseline information to improve program planning and implementation of community preventive health activities; (3) data-driven papers from multiple data collection periods to present findings addressing primary evaluation questions (see Section A.1).

The general analysis approach will include summary tabulations of characteristics associated with the five strategic directions for each awardee, or aggregated across subgroups or all 20 awardees. Cross-tabulations will also summarize data by a number of individual or community attributes such as race, ethnicity, age, sex, or income or by level of funding, geographic location, or average household income. We will monitor changes in indicators for the five strategic directives

specified in the ACA legislation (i.e., weight, proper nutrition, physical activity, tobacco use prevalence, and emotional well-being and mental health) by tabulating the estimated change from baseline and 95% confidence interval for the change in the average level (or prevalence) of a key outcome (e.g., Year 1 to 3 change, Year 1 to 5 change). Once data for all three data collection periods are collected, statistical models can be used to estimate the average annual change or trend in outcomes and to evaluate whether the estimated trend over time is significantly increasing or decreasing for each awardee. The trends across subgroups of awardees or all awardees will also be modeled as a function of awardee characteristics (contextual or implementation/process) including the level of intensity of the CTG Program (“dose” of activities) to identify characteristics most associated with improvements in outcomes. Statistical analysis plans will specify the statistical models to be employed, assumptions made, and exploratory analyses that will be conducted. In all analyses, data will be weighted to account for the unequal probability of selection and response (see Section B.3).

Project Timeline

Exhibit A.16.1 provides a detailed timeline for all data collection described in this ICR.

Exhibit A.16.1. Project Timeline

Activity	Expected Timeline
Internal pilot testing of data collection instruments for <i>Standard</i> and <i>Enhanced Protocols</i>	March 2012–October 2012
OMB Approval	May 2013
Measurement Period #1	
<i>Standard Protocol</i> data collection in 12 awardees (ATSS only)	May 2013–April 2014
<i>Enhanced Protocol</i> and <i>Standard Protocol</i> data collection in 8 awardees (ATSS and Adult and Youth Biometric Measures)	July 2013–June 2014
Data Processing and Analysis	May 2014–March 2015
Measurement Period #2	
<i>Standard Protocol</i> data collection in 12 awardees (ATSS only)	May 2015–April 2016
<i>Enhanced Protocol</i> and <i>Standard Protocol</i> data collection in 8 awardees (ATSS and Adult and Youth Biometric Measures)	July 2015–June 2016
Data Processing and Analysis	May 2016–February 2017
Measurement Period #3	
<i>Standard Protocol</i> data collection in 12 awardees (ATSS only)	May 2017–April 2018
<i>Enhanced Protocol</i> and <i>Standard Protocol</i> data collection in 8 awardees (ATSS and Adult and Youth Biometric Measures)	July 2017–June 2018
Data Processing and Analysis	May 2018–March 2019

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

No request for an exemption from displaying the expiration date for OMB approval is being sought.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

These data will be collected in a manner consistent with the certification statement identified in Item 19, Certification for Paperwork Reduction Act Submissions, of OMB Form 83-I. No exceptions are requested.

A.19 References

1. Centers for Disease Control and Prevention (CDC). (2008). Smoking-attributable mortality, years of potential life lost, and productivity losses—United States, 2000–2004. *Morbidity and Mortality Weekly Report*, 57(45), 1226–1228.
2. Centers for Disease Control and Prevention (CDC). (2011). Vital signs: Current cigarette smoking among adults aged ≥ 18 years—United States, 2005–2010. *Morbidity and Mortality Weekly Report*, 60(35), 1207–1212.
3. Centers for Disease Control and Prevention (CDC). (2010). Vital signs: Nonsmokers' exposure to secondhand smoke—United States, 1999–2008. *Morbidity and Mortality Weekly Report*, 59(35), 1141–1146.
4. Centers for Disease Control and Prevention (CDC). (2012). *Guide to community preventive services: Tobacco use*. Retrieved February 9, 2012, from <http://www.thecommunityguide.org/tobacco/index.html>
5. Centers for Disease Control and Prevention (CDC). (2010). *The community guide: What works to promote health*. Retrieved March 12, 2012, from <http://www.thecommunityguide.org/tobacco/index.html>
6. Hopkins, D. P., Razi, S., Leeks, K. D., Kalra, G. P., Chattopadhyay, S. K., Soler, R. E., & Task Force on Community Preventive Services. (2010, February). Smokefree policies to reduce tobacco use: A systematic review. *American Journal of Preventive Medicine*, 38(2, Suppl.), S275–S289.
7. Dhar, P. (2004). Measuring tobacco smoke exposure: Quantifying nicotine/cotinine concentration in biological samples by colorimetry, chromatography and immunoassay methods. *Journal of Pharmaceutical and Biomedical Analysis*, 35, 155–168.
8. Farrelly, M. C., Nonnemaker, J. M., Chou, R., Hyland, A., Peterson, K. K., & Bauer, U. E. (2005). Changes in hospitality workers' exposure to secondhand smoke following the implementation of New York's smoke-free law. *Tobacco Control*, 14, 236–241.
9. Flegal, K. M., Carroll, M. D., Ogden, C. L., & Curtin, L. R. (2010). Prevalence and trends in obesity among us adults, 1999–2008. *Journal of the American Medical Association*, 303(3), 235–241.
10. Ogden, C. L., Carroll, M. D., & Curtin, L. R. (2010). Prevalence of high body mass index in U.S. children and adolescents, 2007–2008. *Journal of the American Medical Association*, 303(3), 242–249.
11. Ogden C. L., & Carroll M. D. (2010). *Prevalence of overweight, obesity, and extreme obesity among adults: United States, trends 1960–1962 through 2007–2008* (National Center for Health Statistics [NCHS] Health E-Stat). Retrieved from http://www.cdc.gov/nchs/data/hestat/obesity_adult_07_08/obesity_adult_07_08.pdf

12. Li, F., Harmer, P., Cardinal, B., Bosworth, M., & Johnson-Shelton, D. (2009). Obesity and the built environment: Does the density of neighborhood. *American Journal of Health Promotion, 23*(3), 203–209.
13. U.S. Department of Health and Human Services. (2008). *2008 Physical Activity Guidelines for Americans*. Washington, DC: Author.
14. Blair, S. N. (2009, January). Physical inactivity: The biggest public health problem of the 21st century. *British Journal of Sports Medicine, 43*(1), 1–2.
15. Healy, G. N., Clark, B. K., Winkler, E. A., Gardiner, P. A., Brown, W. J., & Matthews, C. E. (2011, August). Measurement of adults' sedentary time in population-based studies. *American Journal of Preventive Medicine, 41*(2), 216–227.
16. Centers for Disease Control and Prevention (CDC), AARP, & American Medical Association. (2009). *Promoting preventive services for adults 50–64: Community and clinical partnerships*. Retrieved February 13, 2012, from <http://www.cdc.gov/aging/pdf/promoting-preventive-services.pdf>.
17. Centers for Disease Control and Prevention (CDC). (2012). Chapter 18: Mental health and mental disorders. In *Healthy people, 2010 (final review)* (pp. 18-1–18-2). Retrieved February 13, 2012 from http://www.cdc.gov/nchs/healthy_people/hp2010/hp2010_final_review.htm
18. Centers for Disease Control and Prevention (CDC). (2001). Increasing physical activity: A report on recommendations of the Task Force on Community Preventive Services. *Morbidity and Mortality Weekly Report, 50*(18), 1–16.
19. Centers for Disease Control and Prevention (CDC). (2012). *Guide to community preventive services: Promoting physical activity*. Retrieved February 13, 2012, from <http://www.thecommunityguide.org/pa/index.html>.
20. August, K. J., & Sorkin, D. H. (2011). Support and influence in the context of diabetes management: Do ethnic differences exist? *Journal of Health Psychology, 16*(5), 711–721.
21. Thompson, W. M., & Barksdale, D. J. (2010). Physical inactivity in female African-American adolescents: Consequences, costs, & care. *Journal of the National Black Nurses Association, 21*(1), 39–45.
22. Centers for Disease Control and Prevention (CDC). (2012). *Guide to community preventive services. Promoting physical activity: Environmental and policy approaches*. Retrieved February 13, 2012, from <http://www.thecommunityguide.org/pa/environmental-policy/index.html>
23. Centers for Disease Control and Prevention (CDC). (2012). *Physical activity resources for health professionals: Active environments*. Retrieved February 13, 2012, from <http://www.cdc.gov/physicalactivity/professionals/environment/index.html>

24. Soler, R. E., Leeks, K. D., Buchanan, L. R., Brownson, R. C., Heath, G. W., Hopkins, D. H., & Task Force on Community Preventive Services. (2010). Point-of-decision prompts to increase stair use: A systematic review update. *American Journal of Preventive Medicine*, 38(2 Suppl.), S292–S300.
25. Centers for Disease Control and Prevention (CDC). (2011). *About the BRFSS*. Retrieved March 13, 2012, from <http://www.cdc.gov/brfss/about.htm>
26. Centers for Disease Control and Prevention (CDC). (2011). *Behavioral Risk Factor Surveillance System Survey questionnaire*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.
27. Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). (2008). *National Health and Nutrition Visit Survey (NHANES) questionnaire—Weigh history questionnaire module*. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention.
28. Bradburn, N. M., Sudman, S., & Wansink, B. (2004). *Asking questions: The definitive guide to questionnaire design—or market research, political polls, and social and health questionnaires*. San Francisco, CA: Jossey-Bass.
29. Centers for Disease Control and Prevention (CDC). (2011). *Youth Risk Behavior Survey*. Retrieved January 5, 2011, from <http://www.cdc.gov/yrbs>
30. Teisl, M. F., Roe, B., & Vayda, M. E. (2006). Incentive effects on response rates, data quality, and survey administration costs. *International Journal of Public Opinion Research*, 18, 364–373.
31. Healy, G. N., Matthew, C. E., Dunstan, D. W., Winkler, E. A. H., & Owen, N. (2011). Sedentary time and cardio-metabolic biomarkers in U.S. adults: NHANES 2003–2006. *European Heart Journal*, 32(5), 590–597.
32. Troiano, R. P., Berrigan, D., Dodd, K. W., Mâsse, L. C., Tilert, T., & McDowell, M. (2008). Physical activity in the United States measured by accelerometer. *Medical Science Sports and Exercise*, 40, 181–188.
33. Centers for Disease Control and Prevention (CDC). (2011). *About the National Health and Nutrition Visit Survey*. Retrieved March 13, 2012, from http://www.cdc.gov/nchs/nhanes/about_nhanes.htm