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

**New**

Supporting Statement

Part A—Justification

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**REFERENCES**

# PART A. JUSTIFICATION

## A1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) supporting an Adult Targeted Surveillance Study (ATSS) and a Youth and Adult Biometric Study (YABS) in up to 20 selected communities/geographic regions funded through the Community Transformation Grant (CTG) Program. Office of Management and Budget (OMB) approval is being requested for the first three years of a six-year project. The Centers for Disease Control and Prevention (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. The information to be collected will enable a multimethod evaluation of the implementation and impact of policy and environmental changes resulting from evidence-based strategies implemented by communities. CDC is authorized to collect data for evaluation by Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1a). In response to this law, The Department of Health and Human Services (HHS) developed an initiative-- the Patient Protection and Affordable Care Act (ACA; Attachment 1b) to revamp our healthcare system from primarily treating disease to maximizing health impact through prevention. CDC is the primary Federal agency for protecting health and promoting quality of life through prevention and control of disease, injury, and disability. CDC is committed to programs that reduce the health and economic consequences of the leading causes of death and disability, thereby ensuring a long, productive, healthy life for all people. Separate requests will be submitted to OMB for related evaluation studies that require data collection. The current information collection request complements two additional requests that have been submitted to OMB for approval: Monitoring and Reporting System for CTG Awardees (pending), and Use of System Dynamics Modeling and Economic Analysis in Select Communities (OMB No. 0920-0937, exp. 6/30/2015).

In fiscal year 2011, funding of $102.6 million was authorized to the CTG Program (CDC-RFA-DP11-1103PPHF11) to finance national networks of community-based organizations. A national evaluation of the CTG Program will be conducted that includes targeted surveillance and a series of special studies that will be implemented over the 6-year period. For the national evaluation, the ACA requires that measures for each of the five strategic directives be collected and assessed over time through targeted surveillance and special and enhanced evaluation studies (Attachment 4): (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, and 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 (SHS) exposure.[1] Nearly one in five adults (19.3%) is a current smoker[2] and 40.1 percent of nonsmokers are exposed to SHS.[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 SHS include increasing the cost of tobacco products, adopting and implementing smoke-free policies, and implementing anti-tobacco media campaigns, 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 SHS exposure, such as enzyme immunoassays to measure cotinine. Cotinine is a validated measure of exposure to smoking[7] 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 percent of adults and 17 percent 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, the U.S. Department of Health and Human Services released the first official government physical activity guidelines in 2008, recommending at least 150 minutes per week of moderate intensity, or 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 studies described in this ICR include 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 1 in 4 Americans between the ages of 50 and 64 is estimated to be up to date in receiving these services. This rate has remained virtually unchanged since 2002.[17]

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 percent less likely than their high-income counterparts to have received cholesterol screening in the past 5 years. Adults with low income are also 30 percent 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.[17] 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 people with mental illness are more likely to be at risk for chronic medical diseases. In 2004, an estimated 25 percent of adults in the United States reported having a mental illness in the previous year.[2] It is also estimated that approximately 50 percent of U.S. adults will develop at least one mental illness during their lifetime. Consequently, the economic burden in 2002 equated to 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 and over had the highest (best) rate of treatment for serious mental illness, 68 percent in 2002, whereas Hispanic or Latino and black non-Hispanic adults had rates of 45 percent and 51 percent in 2002, respectively.[18] Disparities also exist within the unemployment rate by gender—women with serious mental illnesses were 1.5 times more likely to be unemployed than their male counterparts—60 percent vs. 46 percent in 2002.[18]

In past years, the term mental health has been associated with mental illness. As a result, resources have focused primarily on screening for mental illness as opposed to mental health. Researchers have realized the importance of focusing on different domains within the mental health sector, which encompasses both social and emotional well-being. There is a correlation between social and emotional well-being and healthy living among children and adults. Higher levels of well-being are associated with decreased risk of

disease, illness, and injury; better immune functioning; speedier recovery; and increased longevity. Individuals with high levels of well-being are more productive at work and are more likely to contribute to their communities.[4] However, these findings are from individual studies and there are no surveillance efforts to assess these issues such as the CTG Program targeted surveillance will provide.[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.[19] 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).[20] This is an improvement over the last decade when only 25 percent 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 percent of grade 9–12 students received moderate-intensity physical activity.[19] However, disparities persist in the United States with respect to rates of chronic disease and physical activity levels.[21,22] This can 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.[2323] There is a growing body of evidence that supports such approaches, and benefits all persons exposed to the environment rather than focusing on changing physical activity at the individual level.[24] These approaches hold particular promise for promoting physical activity and should be taken into account when designing physical activity interventions.[2424] Other promising strategies to increase physical activity include implementing design and land use policies and practices that support physical activity in urban areas, creating or enhancing access to places for physical activity, and installing point-of-decision prompts to encourage people to use stairs rather than an elevator or escalator.[23,25] In addition, transportation and travel policies and practices can encourage walking and bicycling as alternative means of transportation.

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

The evaluation plan for the CTG Program fulfills the requirements and goals established in Section 4201 of the ACA by providing ongoing surveillance of the five key outcomes specified in the Act (i.e., weight, proper nutrition, physical activity, tobacco use prevelance, and emotional well-being and mental health) and provides for a robust and multicomponent evaluation of CTG activities; short-term and intermediate changes; changes in other nonbehavioral risk factors and related health outcomes; and intervention characteristics, the policy environment, and health-related costs and savings. The overall CTG evaluation plan will use multiple evaluation approaches (Attachment 4) to assess the degree to which activities and strategies selected by CTG Program awardees result in changes that increase health equity, eliminate health disparities, and improve the health of all groups.

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 five core variables included in the Affordable Care Act legislation. Although there are multiple components of the evaluation plan, this OMB package requests approval for only two components: an Adult Targeted Surveillance Study and a Youth and Adult Biometric Study (Exhibit A-1-1).

The ***Adult Targeted Surveillance Study (ATSS)*** will collect survey data in a representative sample of residents living in specific geographic areas where a select subset of the CTG Program awardees are implementing interventions that address the aforementioned Strategic Directives. The ATSS has been designed to assess changes in attitudes, behavioral risk factors, and health outcomes related to the five strategic directives using items from existing national and state data systems such as the state-based BRFSS. The interview will collect information about the adult respondent (e.g., height, weight, tobacco use) and about the household nutrition, activity, and smoking-related practices (e.g., limiting sedentary time, frequency of meals at full-service and fastfood restaurants, smokefree home rules). The ATSS will be conducted in areas targeted for interventions by 20 awardees (10 initiated in Year 1; 10 initiated in Year 2). Data from the ATSS will be compared with existing data from the BRFSS for the county or state in which the area is located and also compared with estimates from other existing state and national surveillance systems.

The ***Youth and Adult Biometric Study (YABS)*** will assess the changes in biometric markers of health status in adults and children by conducting an in-home examination to collect weight, height, waist circumference, and blood pressure (adults only) measurements, and a saliva sample to determine SHS exposure. A subsample of adult and youth pairs from the same household will be asked to wear a tri-axial accelerometer, the Actigraph GT3XE, a small, lightweight device worn on a belt around the waist to provide objective measures of the duration and intensity of physical activity and sedentary behavior over 7 days. Accelerometers measure and record time-stamped acceleration in one or more directions (e.g., uniaxial, triaxial, omnidirectional), thereby capturing time spent in various levels of movement or activity intensity. Interviews will be conducted with youth aged 12–17 to assess changes in their knowledge, attitudes, and behaviors, and with caregivers to assess changes in food and activity behaviors and access to safe areas to play for children 3–11 years of age. The in-home data collection will be conducted in the same geographic areas targeted by 8 of the 20 CTG Program awardees taking part in the ATSS (4 initiated Year 1; 4 initiated in Year 2) and will follow the same biennial schedule of observation. After reviewing completeness of accelerometry data provided by participants (> 4 days of data with at least 10 hours of nonzero activity), participants who have not fulfilled criteria for complete data will be asked to wear the accelerometer for an additional 7 days. Adults will maintain a diary for themselves and younger children recording the time of getting up in the morning and going to bed for sleeping and the time and reason the device was removed for 5 minutes or more for any activity such as swimming, or showering; older children will complete

their own diary. Participants will be drawn from two samples of households: (1) a sub-sample of ATSS-respondent households that have at least one child 3 years of age and older; and (2) additional households sampled from an address listing that contains households with children in school catchment areas of high interest for assessing the CTG Program interventions targeted to prevent childhood obesity (see Part B for more details on sampling).

Separate OMB packages will be submitted for other CTG evaluation studies that require data collection.

The specific Research Aims of the proposed studies 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-funded communities per appropriations. Data collection activities will include:
    a. Conduct the ATSS biennially in a representative sample of residents living in geographic areas targeted for interventions by 20 CTG Program awardees (surveys will be conducted in 10 selected awardees in Years 1, 3, and 5, and another 10 selected awardees in Years 2, 4, and 6). The same instruments and sampling designs will be used each year of the ATSS administration.
    b. Obtain biometric measurements and conduct youth and caregiver interviews as part of the YABS in the same geographic areas targeted by 8 of the 20 CTG Program awardees taking part in the ATSS.
2. Assess the reduction in health disparities within special populations for high-interest indicators in CTG-funded communities. Data collection activities will include:
    a Oversampling respondents for the ATSS to allow estimation of changes in high-interest indicators in African American, Hispanic, lower socio-economic, and rural populations.
3. Explore the ways in which individual health is linked to community environmental factors that affect how people live, work, learn, and play.
    a. Behavioral and biometric information on adult-child pairs selected for the YABS will be evaluated in relation to community contextual information and indicators of the CTG Program activities.

**Privacy Impact Assessment Information**

**Overview of Data Collection System**
***Adult Targeted Surveillance Study***

The ATSS is an address-based, multimode survey (telephone interviews or paper survey), conducted with adults aged 18 years and older. The ATSS will be conducted biennially in a representative sample of adult residents living in geographic areas targeted for interventions by 20 CTG Program awardees. The awardees that will participate in the ATSS will be chosen for

their focus on delivering evidence-based programs and content related to diet and physical activity with the goal of reducing childhood obesity. Surveys will be conducted in 10 awardees in Years 1, 3, and 5, and a different set of 10 awardees in Years 2, 4, and 6. The study is quasi-experimental to assess the impact of adoption and implementation of CTG activities on intermediate, long-term, and ultimate health-related outcomes through collection of 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 specific to the five strategic directives for the CTG Program (Section A1), and the eating behaviors, access to physical activity areas and healthy foods, and tobacco use and rules within the household.

***Youth and Adult Biometric Study***

Biometric measurements of youth and adults, and interviews with youth and caregivers will be conducted as part of the YABS in households located in the same geographic areas targeted by 8 of the 20 CTG Program awardees. The YABS will collect (a) quantitative biometric data from in-home examinations of children and adults; (b) in-person survey data from children aged 12–17 or parent/caregiver for children aged 3–11 related to diet and physical activity; (c) individual and household-level characteristics reported by an adult household member (possibly the child's parent/caregiver); (d) data required for interpreting the biometric measures (e.g., whether the person recently lost weight); and (e) accelerometer data in one child (aged 3–17) and one adult pair in a subset of households.

Only one child per household will be selected for the study. If more than one child resides in the participating household, a child who attends middle-school (7th or 8th grade) will be selected with higher probability than other children in the household to allow assessment of the impact of school-based nutrition and physical activity interventions.

Field Interviewers (FI) will collected data contained in the Caregiver Survey, Youth Survey, Adult Biometric Measures, and Youth or Child Biometric Measures instruments using computer-assisted personal interviewing (CAPI), whereby the interviewer uses a computer to read questions and enter respondents' answers.

**Items of Information to be Collected**

Exhibit A-1-1 provides a summary of the content of the data collection instruments to be administered through this project and specifies the sample for each. The topics to be addressed by the various data collection instruments are described below.

***Adult Targeted Surveillance Study***

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.

Questions on the survey were selected to avoid topics that might be sensitive in nature (e.g., embarrassing, very private, or involving illegal behavior). Items have been drawn from existing data sources with valid measures, including from the state-based BRFSS[26] and National Health and Nutrition Examination Survey (NHANES). [27]

*Youth and Adult Biometric Study*

**Interview**: The YABS will comprise households in which an adult has completed the ATSS and has also consented to a home visit. Households with children will be oversampled to ensure an adequate number of youth and child biometric measures and surveys are obtained. If the household has more than one child, only one is selected to participate in the YABS. A parent/guardian must provide consent to conduct the survey with or without his or her presence. When the selected child is 12–17 years of age, the interviewer will administer the Youth Survey, an in-person survey to the child to collect self-reported eating, physical activity, and tobacco use behaviors. Questions will include assessment of the frequency of consumption of sugar drinks including fruit juice, foods with high sugar and fat content, and consumption of healthy foods such as fresh vegetables. In addition, the amount and intensity of physical activity, and use of tobacco and exposure to SHS will be assessed. 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. Once the Youth Survey or Caregiver Survey is completed, biometric data (same for all children 3-17 years of age) will be collected by the FI and entered into a standardized (electronic) form.

**Anthropometric Measures:** Body mass index (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, cardiovascular disease) in adults and in children and adolescents. Decrease in obesity is one of the ultimate outcomes we envision from CTG activities. Anthropometrics will be measured on all participants (youth and adult) of the YABS.

**Saliva Cotinine:** Saliva cotinine determinations provide an objective, biologically relevant measure of exposure to SHS in children and adults. The impact of CTG activities on tobacco use and SHS exposure can be assessed by comparing average cotinine levels prior to initiation of CTG activities with the average levels after implementation. The collection of saliva for cotinine measurements is noninvasive and produces no discernible risk to participants.

**Blood Pressure:** Data on systolic and diastolic blood pressure will be collected from all adult participants in the in-home examination as part of the YABS. Resting heart rate will also be measured on adult participants. As described below, these measures will be used to ascertain hypertension and participants' awareness and treatment of hypertension.

**Accelerometry:** Accelerometry data will be collected from a subset of adult-child dyads living in the same household that have completed other elements of the in-home examination. Accelerometers will collect objective measures of the average time spent engaging in physical activity and inactivity per day. 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.

**Other:** A short list of items will accompany the biometric measurements, such as household smoking, how recently adult participants smoked, weight loss/gain and the date and time of day of data collection. It is expected that decreases in household smoking will be correlated with lower saliva cotinine levels. Accounting for the date and time of the in-home visit will allow adjustment for those potential sources of variability in statistical analysis of these data. Adults with doctor diagnosed hypertension will be asked to provide details specific to their actions in controlling these conditions (e.g., use of antihypertensive medications, reduced salt intake, increased exercise). These items will assess the effectiveness of the CTG strategies in improving awareness of treatment for these conditions.

Exhibit A-1-1 provides an overview of the instruments to be used in the proposed studies, followed by a description for each.

**Exhibit A-1-1. The CTG Program Enhanced Evaluation Instruments for Adult Targeted Surveillance Study and Youth and Adult Biometric Study**

| Study Component | Form Name and Description | Sampling Frame | Domains | Data Collection Mode |
|---|---|---|---|---|
| ATSS | Adult Targeted Surveillance Survey - instrument to obtain household surveillance data on the adults themselves and their household behaviors | 20 awardees, 1,000 per awardee, all adults | • Risk behaviors of the responding adult<br>• 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)<br>• Support for the potential policies or environmental changes they are exposed to in CTG communities (e.g., support for changes in built environment, smokefree policies)<br>• Demographics<br>• Willingness to participate in YABS | CATI, Paper |

| Study Component | Form Name and Description | Sampling Frame | Domains | Data Collection Mode |
|---|---|---|---|---|
| YABS | Adult Biometric Measures—instrument to collect information specific to the biometric measures | 8 awardees, 500 adults per awardee, all who have completed the ATSS and consented to YABS | Questions related to biometric measures:<br>• Recent weight loss<br>• Changes in household or own eating or physical activity behaviors<br>• Changes in personal smoking<br>• Recent diagnoses of high blood pressure, etc. | In-home visit—CAPI instrument administered by field interviewer |
| | Youth Survey and Youth Biometric Measures — instruments to collect child-specific information on related behaviors and biometric data | 8 awardees, ~200 children ages 12–17 years per awardee, all living in household with adult who completed the ATSS and YABS | • Risk behaviors of the child<br>• Knowledge, attitudes, and behaviors specific to policies they may have been exposed to including in their school<br>• Questions specific to the biometric data to be collected including exposure to SHS, recent weight loss/gain, diagnoses of any comorbidities | In-home visit—CAPI instrument administered by field interviewer |
| | Caregiver Survey and Child Biometric Measures — instruments to collect eating and physical activity behavior on young children from the parent/ caregiver, and biometric data | 8 awardees, ~200 children ages 3–11 years per awardee, all living in household with adult who completed the ATSS and YABS | • Caregiver survey includes the following topics:<br>– Eating behavior of child in past 24 hours<br>– Physical activity level at home and school<br>– Access to safe areas to play<br>• Questions specific to the biometric data to be collected including exposure to SHS, recent weight loss/gain, diagnoses of any comorbidities | In-home visit—CAPI instrument administered by field interviewer |

**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.

## A2. Purposes and Use of the Information Collection

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 five core variables associated with chronic disease prevention included in the Affordable Care Act legislation. The evaluation plan for CTG fulfills the requirements and goals established in Section 4201 of the ACA and provides for a robust and multicomponent evaluation of CTG activities; short-term and intermediate changes; changes in other nonbehavioral risk factors and related health outcomes; and intervention characteristics, the political environment, and health-related costs and savings. These collective approaches broaden a systems-level design beyond particular settings, such as an individual health care setting, and apply systems development to the entire community.

This data collection will allow CDC to meet the congressional mandate for the CTG program in measuring related health outcomes and evaluate the health benefits of the CTG Program overall and for populations representing an array of demographic and historically underserved and hard-to-reach groups that would not have been possible using existing data sources alone.

The data from the ATSS 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 communities. Third, the ATSS 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. The findings will be provided to awardees of the surveyed communities 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 data in CDC publications, websites, congressional briefings, national conferences, and scientific journals.

## A3. Use of Improved Information Technology and Burden Reduction

Collection of ATSS data will be done by a trained field interviewer (FI) using computer-assisted telephone interviewing (CATI), or by the respondent him- or herself using a paper instrument. CATI and paper approaches are the most appropriate collection methodologies for this purpose.[28] 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. CATI methods also improve data validity by automatically detecting errors or questionable responses in real time. For sample addresses without available telephone numbers, data collection by mail reaches a wider demographic and socioeconomic population than would a web survey, at far less cost than in-person interviewing.

***Youth and Adult Biometric Study***
The Youth Survey and Caregiver Survey questions are also designed to obtain the required information while keeping respondent burden to a minimum. The Youth Survey and Caregiver Survey questions are also designed to obtain the required information while keeping respondent burden to a minimum.

Interviews and biometric data collection activities will be conducted by trained FIs. During household visits, the FI will administer the Youth Survey or the Caregiver Survey on a laptop computer using computer-assisted personal interview (CAPI), an interviewing mode whereby 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 and web-based methods, 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.

## A4. Efforts to Identify Duplication and Use of Similar Information

Although there are other existing surveillance systems (e.g., BRFSS and YRBSS), 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 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, non-white 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 sub-sample), 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 CHIS. The following provides specific information about the data collection instruments proposed for these studies.

***Adult Targeted Surveillance Study***
The ATSS instrument is designed to obtain the required information with minimal respondent burden. The proposed survey items are mainly drawn from longstanding surveillance surveys such as BRFSS, NHANES, and the National Health Interview Survey (NHIS) [OMB No. 0920-0214, exp. 8/31/2014]. A complete list of the survey instruments reviewed for development of the ATSS instrument in this project appears in Attachment 5.

Many of the questions on the ATSS are derived from items used in the BRFSS.[26] The barriers to using data from the BRFSS for evaluation of CTG interventions are the lack of availability to estimate adult health behaviors and health outcomes for specific regions and subgroups.[29] The ATSS sampling design ensures a sufficient sample size in local areas and for specific populations

currently underrepresented in existing surveillance systems or data sources (e.g., African American, Hispanic/Latino, people residing in rural settings). For many states, the state-based BRFSS is the only available source of timely, accurate data on health-related behaviors but the samples are collected on the state level and do not provide community based estimates of behaviors.[30] For this reason, CTG needs to have its own population surveillance to assess eating behavior changes over time. In terms of CTG, the awardees will be focusing on implementing evidence-based interventions in Year 1 that address childhood obesity so will have local-level change on these two areas of key outcomes. Although much is known about the different levels of influence that have contributed to the obesity epidemic, there is very little evidence that links different types of jurisdiction-wide strategies, like those being implemented by the CTG Program, to long-term health outcomes like reduced obesity. Additionally, existing surveillance systems lack sufficient data on weight, nutrition, and physical activity behaviors among children below ninth grade.

Because the ATSS questions are derived from BRFSS and other state- and nationally based surveillance systems (e.g., BRFSS, Youth Risk Behavior Surveillance System [YRBSS] and the National Youth Risk Behavior Survey, [OMB No. 0920-0493, exp. 1/30/2011], NHANES [OMB No. 0920-0237, exp. 11/30/2012], National Survey on Drug Use and Health [NSDUH, 0930-0110, exp. 8/31/2014]), CDC is able to use data from these sources as a comparison against which to compare trends found in the CTG communities, thus minimizing the burden of requiring data collection in non-CTG comparison areas. In addition, because each community questionnaire is identical, the CTG communities serve as control communities for each other, further minimizing the data collection burden.

***Youth and Adult Biometric Study***

As with the ATSS, many questions on the Youth Survey or Caregiver Survey are derived from items used in existing surveillance systems (e.g., YRBSS, National Survey of Children's Health [NSCH; OMB No. 0920-0406, exp. 04/30/14).[31,32] Those items for the Caregiver Survey are largely drawn from and NSCH, NHIS, and NHANES) (Attachment 5). Existing surveillance systems that provide biometric measurements in adults and children, such as NHANES, were not designed to provide estimates at the level of geographic specificity required to inform the evaluation of CTG interventions and their effect on long-term and ultimate health outcomes. In addition, the objective measurement of height and weight, blood pressure, accelerometry-measured physical activity, and exposure to smoke that will be collected as part of the adult, youth, and child biometric studies has only ever been done at the state level in select geographic areas such as the California Health Interview Survey (CHIS) or as part of a demonstration project[33] or at the national level in the NHANES.[27] The unique nature of the in-home child surveys and biometric data collection will allow CDC to monitor the effects of CTG interventions on changes in objectively measured weight, blood pressure, physical activity, and exposure to SHS, and behaviors and risk factors in children that would otherwise not be possible using existing data sources.

The unique nature of this data collection effort precludes the use of similar data from other data sources. The National CTG Evaluation will strive to collect new information on the effects of CTG interventions on changing behaviors and risk factors with the goal of advancing the state of knowledge on how intervention strategies vary in their effectiveness in different settings, and what factors help explain this variability.

## A5. 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 communities participating in the CTG.

## A6. Consequences of Collecting the Information Less Frequently

***Adult Targeted Surveillance Study***

The data collection in ATSS will consist of biennial surveys in specific geographic areas where each of 10 selected CTG Program awardees are implementing interventions in Years 1, 3, and 5, and in areas targeted by another 10 awardees in Years 2, 4, and 6. 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. Each year a random sample of residents in the specific geographic areas targeted for surveillance is selected. Given the size and population of most of the geographic areas, it is very unlikely that the same resident will be surveyed more than once over the years.

***Youth and Adult Biometric Study***

The in-home data collection will be conducted in some of the same geographic areas targeted for the ATSS and will follow the same biennial schedule of observation. As with the ATSS, 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. Given the size and population of most of the geographic areas, it is very unlikely that the same household will be selected for an in-home examination more than once over the years.

## A7. 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.

## A8. 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 (SMEs) 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 early feedback for each instrument is provided below. Additional experts have also been asked to review the instruments to ensure face validity, appropriate skip patterns, etc.

***Adult Targeted Surveillance Study***

**Subject Matter Experts at CDC Consulted for the Study**

| Name | Organization | Contact Information |
|---|---|---|
| Kristine Day, MPH | Division of Community Health; National Center for Chronic Disease Prevention and Health Promotion | Phone: 770-488-5446 kday@cdc.gov |
| Charlotte Kent, PhD | Division of Community Health; National Center for Chronic Disease Prevention and Health Promotion | Phone: 770-488-6471 Cgk3@cdc.gov |
| Brian King, PhD | Office of Smoking and Health; National Center for Chronic Disease Prevention and Health Promotion | Phone: 770-488-5107 baking@cdc.gov |
| Youlian Liao, MD | Division of Community Health; National Center for Chronic Disease Prevention and Health Promotion | Phone:770-488-5299 Ycl1@cdc.gov |
| Rashid Njai, PhD | Division of Community Health; National Center for Chronic Disease Prevention and Health Promotion | Phone: 770-588-5215 rnjai@cdc.gov |
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| Paul Siegel, MD, MPH | Division of Community Health; National Center for Chronic Disease Prevention and Health Promotion | Phone: 770-488-5296 pzsiegel@cdc.gov |
| Robin Soler, PhD | Division of Community Health; National Center for Chronic Disease Prevention and Health Promotion | Phone:770-488-5103 rsoler@cdc.gov |

**List of Individuals and Organizations Consulted for the ATSS**

| Name | Organization | Contact Information |
|---|---|---|
| Joanne Arsenault | RTI, International | Phone: 919-541-8065 jarsenault@rti.org |
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| Frank Chaloupka | University of Illinois at Chicago | Phone: (312) 413-2367 fjc@uic.edu |
| Dan Chapman | ONDIEH/ NCCDPHP CDC | Phone: (770) 488-5463 daniel.chapman@cdc.hhs.gov |
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| Carole Harris, PhD | ICF International | Phone: 404-321-3232<br>Charris5@icfi.org |
| James Hersey | RTI International | Phone: 202-728-2486<br>hersey@rti.org |
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| Rosemarie Kobau MPH | Division of Public Health, Arthritis, Epilepsy, and Well- Being Branch<br>CDC | Phone: (770)488-6087<br>Rosemarie.kobau@cdc.hhs.gov |
| Cathy Lesesne, PhD | ICF International | Phone: 404-321-3232<br>clesesne@icfi.org |
| Megan Lewis, PhD | RTI International | Phone: 919-541-6000<br>melewis@rti.org |
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| Leslie Lytle | University of Minnesota | Phone: 612-624-1818<br>lalytle@umn.edu |
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| James Nonnemaker, PhD | RTI International | Phone: 919-541-7064<br>jnonnemaker@rti.org |
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| Carol Schmitt, PhD | RTI International | Phone: 202-728-2046<br>cschmitt@rti.org |
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*Youth and Adult Biometric Study*

**Subject Matter Experts at CDC Consulted for the Study**

| Name | Organization | Contact Information |
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## A9. Explanation of Any Payment or Gift to Respondents

***Adult Targeted Surveillance Study***

Respondents to the ATSS will receive an incentive of $20 to compensate them for their time. The proposed incentive amount for this study is based on a review of monetary incentives for other recent large-scale state and national surveys administered using CATI that have similar respondent burden.[34] Evidence from the survey research literature also suggests that increasing the amount of the incentive may also have a positive effect on response rates.

We have chosen an incentive that is commonly used in other large-scale surveys of similar kind and length.

Sampled ATSS households will also receive $2 along with their initial invitation letter, as an additional incentive to participate. Small prepaid incentives have been found to produce improvements in screener response rates.[35]

***Youth and Adult Biometric Study***

Adult participants of the in-home examination will receive a $40 incentive, and child participants will receive a $10 incentive to compensate them for their time. It is anticipated that the in-home exam will take on average 30 minutes for adults, 30 minutes for children 12–17 years of age, and 15 minutes for children 3–11 years of age to complete. An additional $20 incentive will be sent to adults and $10 to children who participate in the accelerometer component of the YABS and provide at least 4 days in which the monitor is worn at least 10 hours following the NHANES accelerometry protocol.[36] The incentives will be explained to potential participants during recruitment over the telephone and as part of the informed consent process at the home visit. Proposed incentives are based on both the age of the participant (child vs. adult) and the level of participation. The proposed incentives are slightly lower than for participants of the longer (5.9 hours) NHANES examination,[27] where an incentive of $70 is given to persons aged 16 and older, and $30 is given to children 2–15 years of age. The incentive is also lower than for the Gulf Coast Children's Study, in which the token of appreciation varied from $75–$135 per household, with incremental tokens of appreciation, based on activity and burden, provided for each completed activity. 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 13–17, $30 was given to the participating child.

## A10. Assurance of Confidentiality Provided to Respondents

The data collection plan of these studies has been approved by the Institutional Review Board (IRB) at RTI International (see 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 examinations are trained in procedures for ensuring privacy of participant information. Participant data are primarily collected using the computerized data management system. No paper records of responses to the targeted surveillance survey or in-home examination are generated. 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 through NCCDPHP's Information Systems Security Officer 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, availability, and integrity at the National Institute of Standards and Technology (NIST) "Moderate" level. We have developed an Information System Security Plan (ISSP) based on NIST Special Publication 800-53 controls and other applicable standards to describe administrative, technical, and physical safeguards or controls to maintain data files to protect the security, integrity, and availability of the system and information collected for this project.

The data collection and management systems (CATI, web-based, 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.

***Adult Targeted Surveillance Study***

As respondent information is entered at a workstation it is stored in the database which resides 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 on paper, data collected reside on a private RTI server, which is subject to the RTI Security standards and methods outlined in the project security plan. All data collected by CATI or on paper will be de-identified prior to storage in the central CTG data repository.

***Youth and Adult Biometric Study***

For the CAPI interviews, information will be collected on laptops using procedures that incorporate both operational and technical controls. Study data on field devices such as laptops will be encrypted to FIPS 140-2 standards and are further protected in transit by SSL.

Accelerometers will be returned in a prepaid envelope to RTI. The security of the data (step counts and acceleration counts) is ensured by labeling the data filename with the participant's study ID. No personal identifiers can be stored on the devices.

Informed consent forms will be sent to RTI by FedEx. Record of action forms will not contain the name of the study or the study ID.

**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 Health and Human Services, 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**

***Adult Targeted Surveillance Study***

Consent will be obtained from each participant prior to administering the ATSS (Attachments 6A, 6B). For surveys conducted via telephone, the interviewer will read an informed consent "script" written on the actual survey document. The participant will then give his or her verbal consent to proceed with the survey. Paper consent forms will be mailed with the paper questionnaire, with separate response envelopes. The consent document will include a comprehensive description/purpose of the study, statement emphasizing the voluntary nature of the study, duration of the survey, incentives, 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.

***Youth and Adult Biometric Study***

During the YABS, the Field Interviewer (FI) will obtain informed consent for the overall study including the Caregiver Survey or Youth Survey, the Adults Biometric Measures, and the Youth or Child Biometric Meaures (Attachments 6C, 6D, 6E). A copy of the written informed consent for the entire study will be provided to the participant for review prior to the start of the home visit. The consent document will include a description of the entire 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 is read to the child, 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 and opt out of any part of the study without penalty at any time. The signed consent documents will be returned to the Study Coordinator by the FI. 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 ATSS and the YABS is voluntary.

## A11. 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 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 examination 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 examination 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 of a somewhat sensitive nature. 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 including those with low socioeconomic status.

The instruments used will ask questions that are consistent with the risk factors the CTG Program seeks to modify. Therefore, questions are asked of persons 9 years of age and older concerning the use of tobacco and exposure to SHS. Similar questions are asked in many national surveys of adults and youth (e.g., NATS and 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. The privacy safeguards above 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 examination is explicitly discussed in the informed consent document (Attachment 6). Saliva will be collected in persons 3 years of age and older to measure level of cotinine. This specimen is necessary to provide a measure of exposure to SHS in children 3–11 years of age, for whom self-report measures are not reliable, and for all participants to allow evaluation of the effect of the CTG Program on an objective measure of this risk factor.

## A12. Estimated Annualized Burden Hours and Cost to Respondents

OMB approval is requested for three years. Annualized estimates are presented in Exhibit A.12-1.

The Adult Targeted Surveillance Survey (ATSS) will be administered to 10,000 respondents in English (Attachment 8A) or Spanish (Attachment S8A) by computer-assisted telephone interview (CATI). Prior to completing the ATSS, respondents will undergo a brief screening interview in English (Attachment 11G) or Spanish (Attachment S11G). The estimated burden per respondent is 2 minutes for screening and 28 minutes for the ATSS.

The Adult Biometric Measures will be collected from 2,000 adult respondents in English (Attachment 12A) or Spanish (Attachment S12A) at the time of the home visit. Prior to completing the Adult Biometric Measures, respondents will undergo a brief screening interview at the time of ATSS participation by phone or mail in English (Attachment 10) or Spanish (Attachment S10). Participants will also undergo a brief screening in person at the time of the home visit in English (Attachment 11F) or Spanish (Attachment S11F). The estimated burden per respondent is 8 minutes for the phone/mail screening, 2 minutes for the in-person screening, and 30 minutes for collection of the Adult Biometric Measures.

The Caregiver Survey Recruitment Screener describes the Caregiver Survey and Child Biometric Measures and will be administered to the parent/guardian of 800 child participants who fall in the 3-11 age range (Attachment 11E). After the screener is administered, the parent/guardian will then complete the Caregiver Survey on behalf of their 3-11 year old child (Attachment 9A). Finally, the Child Biometric Measures will be collected from the 3-11 year old child (Attachment

12C). Spanish versions of the information collection instruments are available (see Attachments S11E, S9A, and S12C, respectively). The estimated burden per adult respondent is 2 minutes for the Caregiver Recruitment Screener, and 18 minutes for the Caregiver Survey. The estimated burden per child respondent is 20 minutes for the collection of the Child Biometric Measures.

The Youth Survey Recruitment Screener for the Parent/Guardian describes the Youth Survey and Youth Biometric Measures and will be administered to the parent/guardian of 800 youth participants who fall in the 12-17 age range (Attachment 11C). The Youth Survey Recruitment Screener for Youth will be administered to 800 youth participants and describes the Youth Survey and Youth Biometric Measures in a manner that is appropriate for youth ages 12-17 to understand (Attachment 11D). After the screeners are administered to the parent/guardian and youth participant, the Youth Survey (Attachment 9B) will be administered directly to the youth participant and the Youth Biometric Measures will be collected (Attachment 12B). Spanish versions of the information collection instruments are available (see Attachments S11C, S11D, S9B, and S12B, respectively). The estimated burden per adult respondent is 2 minutes for the parent/guardian screener. The estimated burden per youth respondent is 2 minutes for the youth screener, 16 minutes for the Youth Survey, and 20 minutes for the collection of the Youth Biometric Measures.

The Adult Activity Diary will be administered to 500 adult participants who agree to provide accelerometry data to estimate physical activity (Attachment 13B). Of the 500 adults participants, 250 are expected to have a child between the ages of 3 and 11 and 250 are expected to have a child between the ages of 12 and 17. The Youth Activity Diary (Attachment 13C) will either be completed by the 250 adults with a 3-11 year old child on behalf of thier child or by the 250 youth respondents who fall within the 12-17 age range. Spanish versions of the Adult and Youth Activity Diaries are available (see Attachments S13B, S13C). The estimated burden for an adult with a child between the ages of 3 and 11 to complete the adult and youth activity diaries, including the reminder phone call, is 20 minutes. The estimated burden for a youth respondent between the ages of 12 and 17 to complete the Youth Activity Diary is 10 minutes.

The total annualized burden across the both studies is 8,301 hours. For the 10,000 adults who participate only in the Adult Targeted Surveillance Survey, the total burden hours are 5,000. For the 2,000 adults recruited to participate in the Youth and Adult Biometric Study, the total burden hours would be 1,983 for those who do not also participate in the accelerometry study and provide an Activity Diary, or 2,150 burden hours for those 500 adults who do provide an Activity Diary. For the additional 800 adults who also provide responses on behalf of their child aged 3-11 years, the total added burden is 267 hours for those not providing an Activity Diary for the child and 309 hours for those who do. For the 1,600 youth who participate in the Youth and Adult Biometric Study, the 800 youth aged 3-11 years whose parents consent for their participation will experience a total of 533 burden hours. The 800 youth who are aged 12-17 years and participate in the Youth and Adult Biometric Study will have 773 total burden hours if they do not provide an Activity Diary and 815 total burden hours for the 250 youth who do complete an Activity Diary.

**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 hr) | Total Burden (in hr) |
|---|---|---|---|---|---|
| Adults in CTG Awardee Communities | Adult Targeted Surveillance Survey Recruitment Screener | 10,000 | 1 | 2/60 | 333 |
| | Adult Targeted Surveillance Survey | 10,000 | 1 | 28/60 | 4,667 |
| Adults Participants in the Youth and Adult Biometric Study | Adult Targeted Surveillance Survey Recruitment Screener | 1,300 | 1 | 2/60 | 43 |
| | Adult Targeted Surveillance Survey | 1,300 | 1 | 28/60 | 607 |
| | Adult Biometric Measures Recruitment Screener (phone/paper) | 2,000 | 1 | 8/60 | 267 |
| | Adult Biometric Measures Recruitment Screener (in-person) | 2,000 | 1 | 2/60 | 66 |
| | Youth Survey Recruitment Screener for Parent/Guardian | 800 | 1 | 2/60 | 27 |
| | Adult Biometric Measures | 2,000 | 1 | 30/60 | 1,000 |
| | Adult Activity Diary and Reminder | 500 | 1 | 20/60 | 167 |
| | Caregiver Survey Recruitment Screener | 800 | 1 | 2/60 | 27 |
| | Caregiver Survey | 800 | 1 | 18/60 | 240 |
| | Caregiver Activity Diary (on behalf of young child) | 250 | 1 | 10/60 | 42 |
| Children Participants in the Youth and Adult Biometric Study | Child or Youth Biometric Measures | 1,600 | 1 | 20/60 | 533 |
| | Youth Activity Diary | 250 | 1 | 10/60 | 42 |

| | | | | | |
|---|---|---|---|---|---|
| | Youth Survey Recruitment Screener for Youth | 800 | 1 | 2/60 | 27 |
| | Youth Survey | 800 | 1 | 16/60 | 213 |
| | | | | Total | 8,301 |

The cost for adult and child respondents can be calculated in terms of their time in responding to the ATSS and YABS surveys and screeners and 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 U.S., since the respondents are expected to span the entire country. The average hourly wage was determined from US Dept. 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, change from 2009)** by dividing 2010 Total U.S. weekly wages by 40 hours. The combined total estimated respondent burden cost for conducting the ATSS and YABS annualized over the three year study period is $167,162.

**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 hr) | Average Hourly Wage | Total Cost |
|---|---|---|---|---|---|---|
| Adults in CTG Awardee Communities | Adult Targeted Surveillance Survey Recruitment Screener | 10,000 | 1 | 333 | $22.33 | $7,436 |
| | Adult Targeted Surveillance Survey | 10,000 | 1 | 4,667 | $22.33 | $104,214 |
| Adults Participants in the Youth and Adult Biometric Study | Adult Targeted Surveillance Survey Recruitment Screener | 1,300 | 1 | 43 | $22.33 | $960 |
| | Adult Targeted Surveillance Survey | 1,300 | 1 | 607 | $22.33 | $13,554 |
| | Adult Biometric Measures Recruitment Screener (phone/paper) | 2,000 | 1 | 267 | $22.33 | $5,962 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Adult Biometric Measures Recruitment Screener (in-person) | 2,000 | 1 | 66 | $22.33 | $1,474 |
| | Youth Survey Recruitment Screener for Parent/Guardian | 800 | 1 | 27 | $22.33 | $603 |
| | Adult Biometric Measures | 2,000 | 1 | 1,000 | $22.33 | $22,330 |
| | Adult Activity Diary and Reminder | 500 | 1 | 167 | $22.33 | $3,729 |
| | Caregiver Survey Recruitment Screener | 800 | 1 | 27 | $22.33 | $603 |
| | Caregiver Survey | 800 | 1 | 240 | $22.33 | $5,359 |
| | Caregiver Activity Diary (on behalf of young child) | 250 | 1 | 42 | $22.33 | $938 |
| Children Participants in the Youth and Adult Biometric Study | Child or Youth Biometric Measures | 1,600 | 1 | 533 | N/A | $0 |
| | Youth Activity Diary | 250 | 1 | 42 | N/A | $0 |
| | Youth Survey Recruitment Screener for Youth | 800 | 1 | 27 | N/A | $0 |
| | Youth Survey | 800 | 1 | 213 | N/A | $0 |
| | | | | | Total | $167,162 |

## A13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

No additional costs will be incurred by the respondents.

## A14. 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 3 years of the project. The annualized cost of the contract is $4,997,866.

**The government costs** include personnel costs for federal staff involved in project oversight and development of this Information Collection Request; these efforts involve approximately 10% of a GS-13 public health analyst @$95,000/year ($9,500); 20% of a GS-13 scientist @ $95,000/year ($19,000), and 10% of a GS-14 scientist @110,000 ($11,000). The estimated annualized cost of federal personnel is $39,500.

The total annulized cost to the Federal government is $5,037,366.

## A15. Explanation for Program Changes or Adjustments

This is a new information collection request supporting evaluatin of a new programmatic initiative.

## A16. Plans for Tabulation and Publication and Project Time Schedule

***Adult Targeted Surveillance Study***

Design: The design of the ATSS and YABS consists of repeated cross-sectional sampling within a set of awardees in Year 1 and a new set of awardees in Year 2. Subsequently, a different sample of individuals from these same awardees will be gathered in Years 3 and 5 (from Year 1 awardees) and in Years 4 and 6 (from Year 2 awardees). We will be able to compute changes in variables of interest over time (3 time points per awardee). These changes will be computed and reported as (1) absolute changes (e.g., changes in BMI from Year 1 to Year 3 to Year 5 reported as $Kg/M^2$); and (2) changes in key measures in relation to measures of the intensity of CTG activities ("dose" of implementation of CTG activities) within each awardee.

Sampling (see Part B for more details): Within awardees, sampling for targeted surveillance and enhanced evaluation studies will be probability based and allow calculation of sample weights. Sampling weights in turn will allow post-stratification computation of indicator estimates and changes in these indicators over time.

Analysis Plan: As stated above, initial analyses will include summary tabulations of respondent characteristics, by awardee and for all respondents, and by key demographic and community characteristics such as race, ethnicity, age, gender, socio-economic factors, and geographic location. Program effectiveness will be analyzed by summary statistics (e.g., change in average BMI from Year 1 to Year 5) and confidence intervals, and through statistical modeling that accounts for the sampling design (hierarchical methods). The CTG Program effectiveness will be assessed by measures of association (regression coefficients from hierarchical models) that relate changes in key measures (e.g., BMI) to the level of intensity of the CTG Program ("dose" of activities). Statistical analysis plans for each study will specify the statistical models to be employed, assumptions made, and exploratory analyses that will be conducted to assess the CTG Program effectiveness, within awardees and across geographic locations.

***Youth and Adult Biometric Study***

A flowchart illustrating the data collection process for the YABS is displayed as Attachment 7. The comprehensive statistical analysis plan for this project is also discussed in Section B.

Data will be input into SAS data sets at RTI International, checked for errors, and cleaned. SAS statistical software package, version 9.3 (SAS Institute Inc., Cary, NC) and SUDAAN, version 10.0.1 (RTI, Research Triangle Park, NC) will be used for data analysis. P-values for the biometric studies will be two-tailed and descriptive; no adjustments will be made for multiple testing.

Prior to selecting appropriate statistical testing methods, the assumptions for each test will be examined. For example, for parametric tests (e.g., two sample t-tests, linear regression test), the Kolmogorov-Smirnov Test will be used to determine whether the study sample came from a normally distributed population. The Levene test will be used to examine the assumption of equal variances. Data transformation (e.g., log transformation) may be used for any non-normal data. If the normal distribution assumption is still not met after data transformation, a nonparametric statistic may be used. The comprehensive statistical analysis plan for this study includes the following:

1. Examine the baseline (pre-CTG activity) characteristics of participants in the in-home visit biometric studies, by awardee and overall, and by subgroups (gender, age, race/ethnicity, rural/urban).
2. Descriptive statistics of biometric measurements (BMI, waist circumference, cotinine, hypertension) and accelerometry-determined levels of physical activity and sedentary behavior by awardee and for all awardees, by adult/youth, by gender, race/ethnicity and by rural/urban. Absolute changes from baseline will also be computed by awardee and by subgroups above.
3. Evaluate the effect of implementation of the CTG Program awardee activities:
    a. To determine whether the CTG Program activities have affected long-term and ultimate health outcomes, we will compute change variables (e.g., BMI Year 5 versus Year 1) and report descriptive and model-based changes in relation to program implementation intensity ("dose") variables across awardees. Modeling strategies will include hierarchical linear models to account for cluster effects and sampling design.
4. Evaluate whether there is variability in the effect of CTG activities across awardees by examination of awardee-level effects using hierarchical models.
5. Evaluate whether awardee-level variables (contextual or implementation/process) explain variability in effectiveness of CTG activities across awardees through hierarchical models by testing interaction effects.

The biometric measurements obtained during in-home visits will be the primary data source used to estimate effects of CTG activities on these long-term and ultimate health-related outcomes. These measures will be combined with ATSS and household-level assessments to evaluate effects of CTG activities on tobacco use, SHS exposure, dietary changes, and changes in physical activity.

The YABS will also address Strategic Directive 3 by recording existing hypertension and linking these observations with self-reported health status and self-reported use of antihypertensive medications.

Qualitative data from in-home interviews on children ages 12 and above will assess the impact of CTG activities on diet and physical activity.

### A.16.1 Publication Plan

Publication writing groups are currently being formed to address scientific concepts related to data collection and analysis, and the CTG Program Publications and Presentations Committee will be convened to determine policies and procedures for dissemination of the CTG Program research results at scientific conferences and publication of results in scientific journals. Publications will fall into four broad categories: (1) baseline, initial assessment results and design methodologies; (2) impact of CTG activities on key indicators; (3) methodologic evaluations, including statistical methodology and program methodology; and (4) integration of findings across multiple studies to address specific study hypotheses.

Dissemination of the CTG Program design, objectives, and methodologies allows potential and current participants to learn more about CTG activities. This information should enhance participation in current and future CTG activities. Furthermore, dissemination of methodologies employed and key results will allow future research efforts to capitalize on the approaches used by the CTG Program awardees and build on these findings. Once results are approved by CDC and other oversight organizations, we will post results on public websites for examination by the public.

### A.16.2 Project Timeline

Exhibit A-16-1 provides a detailed outline for all data collection described in this ICR.

**Exhibit A-16-1. Project Timeline**

| Activity | Expected Timeline |
|---|---|
| Internal pilot testing of ATSS and YABS instruments | March–June 2012 |
| OMB Approval | July 2012 |
| **Measurement Occasion #1 Group A** | |
| ATSS data collection in Group A awardees | July – November 2012 |
| YABS data collection in Group A YABS awardees | September – November 2012 |
| Group A Data Processing and Analysis | September 2012 – January 2013 |
| **Measurement Occasion #1 Group B** | |
| ATSS data collection in Group B awardees | January – May 2013 |
| YABS data collection in Group B YABS awardees | January – May 2013 |
| Group B Data Processing and Analysis (#1) | May – December 2013 |
| **Measurement Occasion #2 Group A** | |
| ATSS data collection in Group A awardees | July – November 2014 |
| YABS data collection in Group A YABS awardees | July – November 2014 |
| Group A Data Processing and Analysis | October 2014 – January 2015 |
| **Measurement Occasion #2 Group B** | |
| ATSS data collection in Group B (#2) awardees | January – May 2015 |

| Activity | Expected Timeline |
|---|---|
| YABS data collection in Group B (#2) YABS awardees | January – May 2015 |
| Group B Data Processing and Analysis | May – December 2015 |
| **Measurement Occasion #3 Group A** | |
| ATSS data collection in Group A awardees | July – November 2016 |
| YABS data collection in Group A YABS awardees | July – November 2016 |
| Group A Data Processing and Analysis | October 2016 - January 2017 |
| **Measurement Occasion #3 Group B** | |
| ATSS data collection in Group B (#3) awardees | January – May 2017 |
| YABS data collection in Group B (#3) YABS awardees | January – May 2017 |
| Group B Data Processing and Analysis | May – December 2017 |

## A17. Reason(s) Display of OMB Expiration Due is Inappropriate

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

## A18. 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.

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