

Supporting Statement A for
Continuation of NEXT Generation Health Study – NICHD
[OMB No. 0925-0610]

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A1. Circumstances Making the Continued Collection of Information Necessary

Justification for continuing the collection of longitudinal health behavior and health status data in a nationwide study is based on the background, need, and considerations described below. The data collection requested is within the legislative authority of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under the Public Health Service Act (PHS) as amended (42 U.S.C. 285g) which includes “the conduct and support of research, training, health information dissemination and other programs with respect to...child health,...human growth and development...” (Legislative Authority).

OMB approval is being sought for a revision of collection of information, which began in 2010 [OMB No. 0925-0610], in order to collect reliable and valid data on changes in health and health behavior in a nationally representative cohort of U.S. adolescents through 2016. The study is collecting information on adolescent health behaviors and social and environmental contexts for these behaviors annually for seven years beginning in the 2009-2010 school year. African-American youth were oversampled to provide better population estimates for these youth and to provide an adequate sample to examine racial/ethnic differences in longitudinal predictors of health, health behaviors, and health behavior change. Hispanic youth were adequately represented in the sample to not require oversampling. Self-report of health status, health behaviors, and health attitudes will continue to be collected with online and (where necessary) paper surveys. Anthropometric data, genetic information, and neighborhood characteristics are gathered on all participants as well. The study incorporates other data sources to obtain related information on community-level contextual data to support NICHD, the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Alcohol Abuse and

Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the Maternal and Child Health Branch of the Health Resources and Services Administration (HRSA/MCHB) in program requirements that address supportive health environments for adolescents. In addition, a representative subsample of overweight and normal weight adolescents (NEXT Plus) are screened for obesity and driving risk factors. These include: objective assessments of physical activity, sedentary behavior, sleep, and driving; biological and genetic markers including those for obesity, cardiovascular disease, and metabolic syndrome - fasting blood glucose, HbA1c, total cholesterol, triglycerides, LDL-C, HDL, C-reactive protein, uric acid, cotinine, height, weight, waist circumference, blood pressure, and carotid intima-media thickness; assessment of dietary intake.

The purpose of this OMB application is to permit continued collection of longitudinal health behavior and health status data in this cohort of U.S. adolescents for four more years. In addition, up to six best friends nominated by the NEXT Plus cohort in 2013 and 2015 will complete brief surveys of their health behaviors. This is a revision of the previous application because there is a new group of respondents and a revision of the survey forms.

Background. Adolescence is a critical period for the development of unhealthy behavioral patterns that may be associated with subsequent adolescent and adult morbidity and mortality. Accurate estimation of adolescents' health status and health-related behaviors and the factors associated with them is useful and necessary for identifying, developing, and evaluating health and education policies, programs, and practices for young people (Currie et al., 2004, 2008). Adolescence is also a critical period for physiological and behavioral changes and for the onset of obesity and substance use (Expert Panel on Integrated Guidelines for Cardiovascular

Health and Risk Reduction in Children and Adolescents, 2011). The influence of social (e.g., peer and social networks) and physical environmental (e.g., community programs, policies, and resources) factors increase during this period as adolescents spend more time outside the family environment. There is growing evidence of the influence of peers and social networks on obesity, substance use, dating violence, and driving in adolescence and early adulthood. Youth from low-income families are especially at risk. Many studies have found consistently increasing gradients of risk factor exposure among those of low socio-economic status (Goodman et al, 2007; Krieger, 2007).

Currently in the U.S., the major assessments of youth health and health risk behaviors either focus on health status (National Health and Nutrition Examination Survey [NHANES; OMB No.: 0920-0237, exp. date: 11/30/2012], National Health Interview Survey [NHIS; OMB No.: 0920-0214, exp. date: 1/31/2013], and Youth Risk Behavior Surveillance [YRBS; OMB No.: 0920-0493, exp. date: 11/30/2011, Grunbaum et al., 2004]) or on substance use of adolescents (National Survey on Drug Use and Health [NSDUH; OMB No. 0930-0080, exp. date 7/31/2013]; Monitoring the Future [Johnston et al., 2009]). The Health Behaviors in School-age Children Survey (HBSC; OMB No.: 0925-0557, exp. date: 1/31/2012), established in 1982, assessed health status in 40+ countries including the US, but also assessed health behaviors and the psychological, social, and contextual influences on these health behaviors.

All of the surveys mentioned above are cross-sectional. Cross-sectional studies are useful for identifying current prevalence of health problems and current rates of health-related behaviors. Repeating these cross-sectional surveys over time provides data for national trend analyses. However, cross-sectional data cannot be used to identify individual changes (growth

curves) over time, to make causal inferences about relationships between socio-cultural and environmental influences on health-related behaviors, or to examine how changes in these influences over time relate to the incidence of risk behaviors or to concurrent changes in positive health behaviors and health outcomes.

Previous longitudinal studies of U.S. children and adolescence have included the Muscatine Coronary Risk Factor Project, Bogalusa Heart Study, the NHLBI Growth and Health Study (NGHS), the Fels Longitudinal Study, and the National Longitudinal Study of Adolescent Health (Add Health). The value of these studies is evident. For example, with regard to obesity and cardiovascular disease (CVD), several important findings have resulted from longitudinal studies, including: the knowledge that atherosclerosis begins in childhood and is strongly related to the number and severity of risk factors; the tracking of childhood obesity, physical inactivity and poor dietary practices into adulthood; the positive association between body weight in childhood and cardiovascular disease risk factors in adulthood; and the association of childhood measures of LDL-C and BMI with carotid artery intima-media thickness in young adults. Although Add Health was effective in examining broad changes in other adolescent risk behaviors and potential determinants, it did not monitor annual changes in health behaviors, their determinants, and their effect on health; nor was it able to link annual changes in behaviors to year-to-year changes in these outcomes. In addition, most of these U.S. longitudinal studies were conducted in the 1980s. They provided insufficient data on environmental influences on physical activity, diet, substance use, and other risk behaviors or did not examine social and contextual influences more broadly (i.e., peer, family and neighborhood influences). There are still gaps in our knowledge of the genetic, physiological, behavioral and environmental (e.g., physical and

social) influences in the development of obesity and cardiovascular disease, substance use, and violence/aggression during adolescence. Data are needed that integrate behavioral factors with genetic, biological and environmental factors in youth in light of many recent scientific advances in genetic, biological, behavioral and environmental sciences. Additionally, it is likely that environmental and psychosocial exposures have changed since the classic adolescent longitudinal studies.

The NEXT Generation Health Study (NEXT) [OMB No. 0925-0610] follows a cohort of 10th-grade students for four years. This application is to continue the study in the fourth wave and extend it for an additional three waves so that we can track this cohort through early adulthood, permitting a unique opportunity to examine predictors of changes in health behaviors and mental health during significant family and career/education transitions. In order to better study the influence of peers and the social context for the health risks of interest, up to six best friends of the NEXT Plus cohort will be asked to complete a brief survey of their health behaviors in 2013 and 2015.

Need. The collection of longitudinal health behavior data in a cohort of U.S. adolescents as they move into adulthood, in combination with school health program and community context data provides a unique source of data for evidence-based research supporting the missions of NHLBI, NIAAA, NIDA, HRSA/MCHB, and the Prevention Research Branch (PRB) of NICHD. NICHD/PRB is responsible for the conduct of research on the cause and prevention of childhood disease and injuries and the prevention of behaviors leading to poor health outcomes among adolescents. The strategic goals of NHLBI include evaluating approaches that encourage and support lifestyle changes that reduce the risk of obesity and cardiovascular disease. NIAAA is

interested in the etiology of adolescent alcohol use, particularly binge drinking, and the role of peer networks in this process as well as the potential preventive efforts of physicians. NIDA is interested in the etiology of adolescent substance use, adolescent substance use when driving, and the role of peers in this process. HRSA/MCHB has the primary responsibility for promoting and improving the health of adolescents through program and policy; this longitudinal study of adolescent health and health behaviors will enable them to identify program and policy needs including issues such as access to health care in urban and rural settings. NEXT results will have significant implications for program and policy development, health education, public information campaigns, demonstration programs, professional education/training, and research activities. The goal of NEXT is to use information to improve long-term health consequences resulting from adolescent behavior and the quality of health programs and services for youth. These goals are consistent with the major U.S. goals and objectives of performance measures for adolescents in Healthy People 2020, NICHD/PRB, and HRSA/MCHB. The foci of NICHD/PRB, NHLBI, NIAAA, and NIDA include adolescent health and behavioral research as priorities in their research initiatives. The program initiatives of the HRSA/MCHB Branches of Adolescent Health and of Injury and Emergency Medical Services address the same goals, including the Government Performance and Results Act (GRPA) requirements for measurable objectives. The HRSA/MCHB Office of Data and Information Management (ODIM) has responsibility for research and program data to guide HRSA/MCHB program areas in meeting their measurable objectives.

Considerations. The following considerations are important for the efficient and timely completion of the NEXT study. The NEXT survey is administered in the beginning months of

the calendar year. Staffing and training of staff is coordinated around this schedule and it is important that measures be completed in approximately the same time frame each year (or wave of the study). Delay in OMB approval could disrupt this schedule and threaten the design of the study. In order to keep the study timeline synchronized with previous waves (for example, permitting comparisons across longitudinal waves), it is essential that the NEXT survey be conducted during the first quarter of 2013. In addition, the study is designed to capture friendship formation in the first and third years after graduation from high school, i.e., Wave 4 in early 2013 and Wave 6 in early 2015. For these reasons, we are requesting OMB approval to continue survey administration on January 1, 2013.

This is a request for OMB clearance of the continuation of the NEXT Generation Health Study.

A2. Purpose and Use of Information

Survey Objectives and Information to be Collected. The 2010-2016 U.S. NEXT Generation Health Study fills significant gaps in current research on adolescence in the U.S. There are no current longitudinal surveys of obesogenic behaviors, substance use, dating violence, and risky driving and their determinants during this critical developmental period. Both survey and non-survey assessments designed to provide information about areas of specific national interest are included. The overall goals of the longitudinal study are to:

1. Identify the trajectories of adolescent health behaviors, including healthful diet and physical activity, sleep, substance use, dating violence, driving, and health status, including obesity, metabolic syndrome, and injuries due to motor vehicle crashes or dating violence, from adolescence through the post-high-school years.

2. Identify individual, family, school, social, and environmental factors (e.g., access to recreational resources, walker/biker friendly neighborhoods) that promote or sustain positive health, positive health behaviors and mental health.
3. Identify transition points in health risk behaviors and risk indicators.
4. Identify changes in individual, family, school, work, and social/environmental precursors to developmental changes in diet, physical activity, sleep, substance use, dating violence, risky driving, and other health risk factors.
5. Examine the role of peer influences on diet, physical activity, sleep, substance use, dating violence, and risky driving, including identifying the direction of causal pathways for peer selection and peer influence.
6. Explore gene-behavior interactions which might serve as the basis for interventions for those identified as at risk for obesity or substance use.

In addition to the survey of health status, health behaviors and the family, school, and social/environmental factors that promote or sustain these, more extensive assessments are completed for a subsample of adolescents (NEXT Plus). These include:

- Objective assessments of physical activity, sedentary behavior, sleep, and driving
- Biological and genetic markers including those for obesity, cardiovascular disease, and metabolic syndrome - fasting blood glucose, HbA1c, total cholesterol, triglycerides, LDL-C, HDL, C-reactive protein, uric acid, cotinine, height, weight, waist circumference, carotid intima-media thickness, and blood pressure
- Assessment of nutrient intake

Since the last application, NEXT participants have been recruited (sample described below) and

a subsample of NEXT participants (NEXT Plus) have been recruited (sample described below) to complete the additional assessments noted above. NEXT participants have completed three annual surveys, had their height, weight and waist circumference measured and provided saliva for genetic assays. NEXT Plus participants have completed periodic assessments of physical activity, sedentary behavior, sleep, and driving and one-time assessments of biological markers for obesity, cardiovascular disease, and metabolic syndrome - fasting blood glucose, HbA1c, total cholesterol, triglycerides, LDL-C, HDL, C-reactive protein, uric acid, cotinine, height, weight, waist circumference, carotid intima-media thickness, and blood pressure.

This application is a revision of the previous NEXT application so that NEXT so that participants can complete an additional four annual surveys through 2016 and for up to six of their best friends to complete one-time surveys in 2013 and 2015. The surveys will be conducted either online or, when necessary, using hard copies. NEXT participants will answer similar questions across all waves to permit the analysis of changes in their behaviors. The NEXT survey is shown in Attachments 1A and 1B. Friends nominated by NEXT Plus participants will complete one-time surveys during the year they are nominated. The NEXT Peer Survey is shown in Attachments 2A and 2B; it includes a subset of the items in the annual survey. The Variable Source Table is available in Attachment 3.

The NEXT Plus participants are screened for factors affecting cardiovascular health and risky driving as well as the influence of peers on physical activity, sedentary behavior, sleep, substance use, dating violence and risky driving. In particular, this substudy more closely examines: adolescent physical activity, sedentary behavior, and sleep and driving patterns; adolescent diet and nutrient intake; biological and genetic markers for obesity and cardiovascular

disease; and peer influences. To assess diet, participants perform a dietary recall on three separate days in each year of the study. Annually, they wear an accelerometer and ActiWatch® for 7 days and concurrently complete a 3-day physical activity diary. Their cars are instrumented with a device that monitors G-force events (changes in speed and/or direction). As part of a battery of in-home assessments performed in years 1, 4 and 7, NEXT Plus participants undergo finger prick blood collection to perform blood analyses, have their height, weight, and waist circumference measured, and have their blood pressure measured. Carotid intima-media thickness of NEXT Plus participants who are overweight or obese will be assessed on one occasion during a home visit.

Linkage of school, work, and home community level information are included to provide data from available data bases on demographic characteristics and proximity of potential influences on health risk and health behavior (e.g., traffic patterns, walkability, food outlets, parks). These data will assist in measuring the social context in which the adolescents function. These factors are associated with the leading health indicators of the U.S. Healthy People 2020, making NEXT extremely relevant for the requirement that U.S. program and policy should be guided by appropriate research and measurable objectives. These are the same research goals as those maintained by NICHD/PRB, NHLBI, NIAAA, and NIDA, and the same program goals held by HRSA/MCHB. Budget has been obligated beginning in FY2012 from the NICHD/PRB and, through inter-agency agreements, from NHLBI, NIAAA, NIDA and HRSA/MCHB to cover the cost of performing the study so as to assist in meeting their program needs.

Receipt and Distribution of Data. The data are collected, merged, and cleaned by The CDM Group and Abt Associates. These organizations deliver a final data set following each

wave of data collection to NICHD/PRB for review and approval. NICHD/PRB delivers the final data set to the collaborating agencies: NHLBI, NIAAA, NIDA, and HRSA/MCHB. NICHD/PRB also is responsible for coordination of use of the data by other Federal agencies and non-governmental organizations for use such as those described below. A public use data set is distributed by NICHD/PRB after the primary research questions have been addressed.

Inter-Agency and Private Sector Use. The NEXT research questions address major gaps identified by Federal Interagency Forum on Child and Family Statistics as U.S. data needs in America's Children, Key National Indicators of Well-being. These include questions on relationships with parents (including non-resident parents), use of time (after school, computers, work, and peer interactions), positive health and behavior attributes (including participation in extracurricular activities), social environment, social inequality, neighborhood environment, and diversity. The latter factors are also addressed by linking Geographic Information System (GIS) software with established databases providing information about neighborhood social, economic, crime, and demographic statistics and using contextual data items on the social environment of the school in the QED and CCD files, including poverty levels measured through multiple options. As a result of the earlier identification of these gaps, a June 14-15, 2001 workshop at NIH recommended that alternative data sources be used to develop measures of influences on positive aspects of child well-being that go beyond current surveillance sources.

Past Uses of the Survey Data. As of the date of this report, manuscripts have been submitted for publication and one has been accepted for publication (Ogbagaber, S., Albert, P. S., Lewin, D. & Iannotti, R. J. (in press). Summer activity patterns among teenage girls: harmonic shape invariant modeling to estimate circadian cycles. Journal of Circadian Rhythms.)

Evaluation Components. The evaluation is completed in two phases:

Analysis of the data supported under contract with The CDM Group.

U.S. research studies on determinants of adolescent health and health behaviors through collaboration of NICHD, NHLBI, NIAAA, NIDA and HRSA/MCHB scientific and post-doctoral personnel.

Appropriateness and adequacy of sample, data collection, and analysis plans. A nationally-representative cohort of U.S students in grade 10 was recruited using a multistage stratified design. Primary sampling units consisted of school districts or groups of school districts stratified across the nine U.S. Census divisions. Within this sampling framework 137 schools were selected and formally recruited; 80 (58.4%) agreed to participate. Tenth-grade classes were randomly selected within each recruited school and 3,796 students were recruited to participate; youth assent and parental consent were obtained from 2,619 (69.0%) students. Of those consented, 2,524 (96.4%) completed the Wave 1 survey. African-American students were oversampled to provide estimates with a precision of plus or minus 3 percentage points at the 95% confidence level; given the prevalence of Hispanic youth in this age group, the cohort already included an adequate sample of Hispanic youth to meet this criterion. In Wave 1, confidential self-report surveys were administered by trained research assistants in the 10th-grade classrooms.

The retention rate from Wave 1 to Wave 2 was 87.1%. Due to a delay in obtaining final OMB approval and subsequent approval from the Chicago Public Schools, 246 students from Chicago Public Schools did not participate in the study until Wave 2. As a result, the Wave 2 sample was 2,454. The sample is 2,209 in Wave 3. In Waves 4 through 7, those 18 or older will be re-consented with young adult consent forms (Attachment 4).

A primary goal of NEXT is to examine the prevalence and determinants of selected health behaviors and health status measures in adolescents, ages 16 through 22, beginning with a nationally representative probability sample of students in grade 10 from public and private schools. The required sample size at the end of wave 7 (in 2016) in terms of the number of completes was estimated based on the desired precision of the estimate of change between two time periods. The sample size should be such that we are able to reject the hypothesis of no difference in population percentages with 80% power using a two-sided statistical test at 5% of level of significance comparing characteristics of interest between two groups (for example meeting recommendations for daily physical activity in normal and overweight youth) given a difference of 5.3 percentage points. The sample was first determined assuming a simple random sample of participants. This gives a sample of around 700 participants. Using a multi-stage sampling design and assuming a design effect of 1.5 (based on previous HBSC surveys), we increased the sample to 1,050 completes in the main sample. The margin of error of the estimated population percentage at 95% confidence level at the end of wave 7 based on a sample size of 700 is plus or minus 3.7 percentage points.

An oversample of African-American youth was also included in order to improve the validity of sub-group analyses and to better study health disparities. The strategy for minority oversampling was based on the requirement of around 215 African-American participants at the end of Wave 7 out of sample of 1,050 completes. Without oversampling, we expected around 180 African-American participants at the end of wave 7. Therefore, insufficient sampling of minorities was expected in the basic sample. To get the additional minority participants, we identified schools with a high percentage of African-American students and recruited additional

students within these schools. Originally, it was planned to select additional primary sampling units for sampling Hispanic students. This plan was not necessary. Hispanic youth did not require oversampling because they represented a sufficient proportion of the population of adolescents to provide an adequate sample to examine racial/ethnic differences. We recruited a sample sufficient to provide 215 Hispanic participants in Wave 7 without oversampling.

Toward these ends, we constructed a sampling frame that included all 10th-grade students in public, private, and parochial schools in the 50 states and the District of Columbia during the 2009-2010 school year. For sampling students from public schools, primary sampling units (PSUs), which were either individual school districts or groups of rural school districts, were selected as a sample of PSUs at the first stage. Private and parochial schools were linked to public districts to ensure that these sampled schools fell within the same sample clusters as sampled public schools.

Sampling Overview for In-Home Substudy (NEXT Plus) (N=560). The sampling frame for the NEXT Plus substudy was all schools successfully recruited to participate in the basic survey. The following sampling stages were implemented: In each of the nine strata (Census Divisions) all schools recruited were listed; Geographic cluster sampling was used to group schools, which were in relatively close geographic proximity, into clusters (or “communities”); On average, two clusters per Census Division were randomly selected for a total of 20 communities; Within each “community” cluster, schools were first sorted by whether they were urban, suburban, and rural schools to assure representation; Two schools within each cluster were then systematically sampled; Each school selected contributed two classrooms that were randomly selected to participate in the basic survey; At the study office, students’ in the selected

classrooms were categorized as “overweight” or “normal weight” based on their height and weight measurements collected during the main study; Seven overweight children and seven normal weight children were randomly selected across classes per school from the respective weight status categories and recruited to the substudy. In Waves 4 through 7, those 18 or older will be re-consented with a young adult consent form (Attachment 4). Participants recruited for the Peer Survey will complete a Peer Survey consent form (Attachment 5) and parents of those younger than 18 will also complete a parent Peer Survey consent form (Attachment 6).

For specific hypotheses, the NEXT Plus subsample will be adequate to address primary hypotheses relating to obesity and cardiovascular disease. Power analysis and sample size estimation for specific hypotheses were conducted using Monte Carlo simulation procedures recommended by Muthen and Muthen (Muthen & Muthen, 2001). Monte Carlo simulation is the most common and preferred method to determine sample size for sufficient statistical power in multivariate analysis and structural equation modeling. In a Monte Carlo simulation, random samples with a specified sample size are generated repeatedly from a population with known parameters consistent with the proposed model. Path coefficients are then estimated from each simulated sample. The percentage of simulated samples that have significant parameters indicates the power of the study. The required sample size can be accurately determined by varying sample sizes in a series of simulations. The Monte Carlo study for determining power and sample sizes for the present study was conducted using Mplus version 3.0, which provides extensive simulation facilities for structural equation modeling.

The power analysis for determining sample sizes was conducted using a latent growth curve model for the relationship between participant physical activity and participant-reported

peer physical activity, i.e., a linear model with seven repeated measures of physical activity as outcome with one-year intervals between the measures. Peer behavior was specified as a covariate with two additional covariates (gender and SES). Simulation was conducted using two peer effect sizes including various corresponding peer behaviors and outcomes in the study (substance use, physical activity, diet, obesity). A smaller effect size was defined by Cohen (1988) as 0.1 in standardized estimate and a medium effects size was 0.3. The path loadings from the intercept to the seven outcome measures were set at 1 and to the slopes were set from 0 to 7 with each unit represents a one year interval of assessment. Missing values were also generated in the simulation with each variable having 15% random missing.

Muthen and Muthen (2001) recommend several criteria for estimating appropriate sample sizes in power analysis for structural equation modeling. Parameter bias should not exceed 10%; standard error bias should not exceed 5%, and the coverage remains between 90 to 98%. The Monte Carlo simulation for this study conducted 1,000 replications with various sample sizes. The results from the simulation indicated that a final sample size of $N = 440$ for the linear model with small effect size had a statistical power of 96% to detect a peer effect, provided that missing values are random and below 15%. A separate simulation with medium effect size indicated that a sample size of $N = 150$ would have a power greater than 90% for detecting a peer effect. As a marker of clinical significance, a 0.3 to 0.5 SD between-group difference in physical activity should have a significant relation to health outcomes such as metabolic syndrome or adiposity. Thus, we would have the power to detect a clinically significant change in adiposity in analyses of the main sample and in analyses of selected subgroups. Subject retention has been higher in the NEXT Plus sample than the NEXT sample.

The larger NEXT sample provides power to examine smaller effects within multilevel models and comparisons across sub-groups of interest. All criteria recommended by Muthen and Muthen (2001) were satisfied for the simulation studies.

Appropriateness of data collection plans. NICHD/PRB has collected 3 waves of data collection beginning in the spring of 2010 (January-June). A general schedule of data collected to date is provided below:

	Grade 10 (Wave 1)	Grade 11 (Wave 2)	Grade 12 (Wave 3)
Entire Sample			
Survey	Spring 2010 (in-school)	Spring 2011 (online or hard copy)	Spring 2012 (online or hard copy)
Anthropometric Assessments (height, weight, waist circumference)	Spring 2010 (in-school)	Spring 2011 (in-school)	Spring 2012 (in-school)
Genetic sampling (saliva sample)	Spring 2010 (in-school)		
NEXT Plus Sub-study			
Physical Activity and Sleep Assessments (Accelerometer, Actiwatch®, 7-day activity log)	Spring-Summer 2010 (7-day monitoring)	Spring-Summer 2011 (7-day monitoring)	Spring-Summer 2012 (7-day monitoring)
Dietary Recall (3-day diet recall)	Spring-Summer 2010 (online)	Spring-Summer 2011 (online)	Spring-Summer 2012 (online)
Blood Analyses (finger prick blood collection)	Spring 2010 (in-school)		

	Grade 10 (Wave 1)	Grade 11 (Wave 2)	Grade 12 (Wave 3)
Height, weight, waist circumference, blood pressure, chronic illness	Spring-Summer 2010 (in-home)		

The continuation of data collection through 2016 is described in the table below:

	<u>First Year Post-high school (Wave 4)</u>	<u>Wave 5</u>	<u>Wave 6</u>	<u>Wave 7</u>
Entire Sample				
Survey	Spring 2013 (online or hard copy)	Spring 2014 (online or hard copy)	Spring 2015 (online or hard copy)	Spring 2016 (online or hard copy)
NEXT Plus Sub-study				
Physical Activity and Sleep (Accelerometer, Actiwatch®, 3-day activity log)	Spring-Summer 2013 (7-day monitoring)	Spring-Summer 2014 (7-day monitoring)	Spring-Summer 2015 (7-day monitoring)	Spring-Summer 2016 (7-day monitoring)
Dietary Recall (3-day diet recall)	Spring-Summer 2013 (online)	Spring-Summer 2014 (online)	Spring-Summer 2015 (online)	Spring-Summer 2016 (online)
Blood Analyses (finger prick blood collection)	Spring-Summer 2013 (in-school)			Spring-Summer 2016 (in-home)
In-home Assessments (height, weight, waist circumference, blood pressure, chronic illness)	Spring-Summer 2013 (in-home)			Spring-Summer 2013 (in-home)
Peer Survey	Spring-Summer 2013		Spring-Summer 2015	

	<u>First Year Post-high school (Wave 4)</u>	<u>Wave 5</u>	<u>Wave 6</u>	<u>Wave 7</u>
Driving Risk	2013	2014	2015	2016
Carotid Intima-Media Thickness			Spring-Summer 2015	

The contract to accomplish data collection was awarded on September 30, 2009 after competitive review, to an experienced research organization. The CDM Group, in collaboration with Abt Associates as its subcontractor, has completed all faces of Waves 1 through 3. The same contractor has been awarded an IDIQ contract to complete tasks related to Waves 4 through 7.

Analytic approach. Analyses have proceeded from preliminary assessments of the quality of the data, to descriptive statistics of the distribution and central tendency of the data, to primary, inferential statistical analyses addressing the research questions.

Outcomes of Interest: The U.S. NEXT longitudinal study fills significant gaps in current research on adolescence in the U.S. There are no current longitudinal surveys of health behaviors, mental health, and their determinants during this critical developmental period. Both survey and non-survey assessments designed to provide information about areas of specific national interest will be included. The analytic goals of the longitudinal study include to:

1. Identify the trajectories of adolescent health behaviors, including healthful diet and physical activity, sleep, substance use, dating violence, driving, and health status, including obesity, metabolic syndrome, and injuries due to motor vehicle crashes or dating violence, from adolescence through the post-high-school years.

2. Identify individual, family, school, social, and environmental factors (e.g., access to recreational resources, walker/biker friendly neighborhoods) that promote or sustain positive health, positive health behaviors and mental health.
3. Identify transition points in health risk behaviors and risk indicators.
4. Identify changes in individual, family, school, work, and social/environmental precursors to developmental changes in diet, physical activity, sleep, substance use, dating violence, risky driving, and other health risk factors.
5. Examine the role of peer influences on diet, physical activity, sleep, substance use, dating violence, and risky driving, including identifying the direction of causal pathways for peer selection and peer influence.
6. Explore gene-behavior interactions which might serve as the basis for interventions for those identified as at risk for obesity or substance use.

Descriptive Statistics. The purpose of descriptive analyses is to obtain a sense of the data, determine possible outliers, and inform the selection of appropriate statistical procedures.

Descriptive procedures include assessment of the distribution, central tendency, dispersion, and normality (skewness, kurtosis, Kolmogorov-Smirnov or Shapiro-Wilkes, boxplots, and graphs), as appropriate for the data. Outliers are checked against original forms to determine whether the values are errors in data entry that can be corrected. Transformation of variables prior to use in subsequent analyses are considered at this point.

Descriptive statistics for relevant groupings, for example, race, sex, gender, and age, are obtained. Typically, logistic and ordinary least squares (OLS) regression analyses are used at

this point, allowing examination of diagnostic data such as graphs of residuals and predictor variables, Cook's distance, and collinearity including condition indices.

Refusals and dropouts. At each wave of assessment, t-test and Chi-square analyses are performed to compare students who dropout of the longitudinal cohort with those who continue.

Missing data. Missing data is particularly problematic in longitudinal studies. Every effort is made to minimize missing data by employing procedures such as immediately reviewing self-administered measures and conducting follow-up telephone calls to identify respondent's intention to complete missing items when appropriate. A minimum of three data points are required for the proposed longitudinal analyses; when a participant has less than three completed assessments on a particular variable, that individual will be excluded from the longitudinal analyses involving that variable. Additional data points will strengthen the analysis and provide a better estimate of health behaviors before and after the high school years.

The Biostatistics and Bioinformatics Branch (BBB) is within our Division and we work closely with branch investigators; for example, at least one investigator from the branch is assigned to every project within the division. Their statistical expertise is being employed to ensure that imputation of missing data is appropriately handled. In general, random missing data can be handled within the software and analysis plan proposed (e.g., the maximum likelihood imputation method offered by Mplus; this is one of the strengths of the proposed analyses). When non-ignorable missing data are identified (e.g., a key outcome variable is differentially related to the presence or absence of missing data), appropriate methods will be used to take these into account during data analyses. Paul Albert, Ph.D, BBB branch chief, is an expert in the area of non-ignorable missing data and will identify the appropriate methods for dealing with

these data. For example, depending on the nature of missingness, analyses could include methods such as shared random parameter models (Albert, 1999; Wu & Carrol, 1988) and selection models (Little, 1987).

Longitudinal Analyses. The study offers an unusual opportunity to assess the determinants of adolescent health, health risk behaviors, and mental health over an extended period and during some critical transitions. One purpose of these analyses would be to identify youth at risk of increasing risk behaviors or decreasing positive health behaviors that diverge from the normal trajectory of these behaviors. Latent growth modeling as a part of Autoregressive Latent Trajectory modeling (ALT) will be used to identify patterns in growth curves and predictors of variations in these developmental patterns. Because many of the variables of interest change over time, examination of the relationships between the intercepts and slopes of the variables of interest would reveal the extent of relationships, with other variables of interest or concern included in the model. Autoregressive models as a part of ALT modeling will be used to examine prospective paths over subsequent waves of assessment. Planned analytic techniques will also enable us to examine normative trends with individual variation from the norm and/or multiple-trajectories to identify homogeneous groups (or types) with similar trajectories within these groups or types.

Examples of research questions that would guide analyses for a variety of outcomes follow.

Obesity and diet:

Research Question 1: What consumption patterns characterize an obesogenic diet? Specifically, does an obesogenic diet include significantly higher consumption of saturated and trans fats, soda, and fried foods, lower consumption of fruits and vegetables, or higher consumption of

carbohydrates with a high glycemic index?

Research Question 2: Do changes in dietary composition precede corresponding changes in body composition and blood glucose levels?

Research Question 3: What are the diet-genetic interactions that affect the expression of genetic risk for obesity?

Research Question 4: Does neighborhood access to fast food outlets provide an obesogenic environment while access to fresh food markets reduces this effect?

Research Question 5: Does regular consumption of breakfast reduce risk for obesity?

Research Question 6: Do family eating patterns (e.g., eating together at primary meals, TV watching during meals) affect risk for obesity?

Research Question 7: Does the transition from high school mark a significant change in dietary composition and quality and in eating patterns (e.g., consumption of breakfast, consumption of fast foods) which has a corresponding effect on risk for obesity?

Research Question 8: To what extent are short-term changes in dietary patterns as a result of the transition out of high school maintained beyond the first year?

Research Question 9: Do transitions in characteristics of peers and peer behaviors and the quality of peer affiliations account for changes in diet?

Physical Activity:

Research Question 1: Does overall energy expenditure from physical activity relate to risk of obesity and does this effect require a threshold level of physical activity?

Research Question 2: Is intensity of physical activity more important than overall energy expenditure; e.g. is vigorous physical activity, independent of overall energy expenditure,

essential for reducing risk of obesity and cardiovascular disease in adolescents and young adults?

Research Question 3: Are certain types of physical activity more likely to result in bouts of vigorous physical activity?

Research Question 4: Do changes in physical activity precede corresponding changes in body composition, lipids, and blood glucose levels?

Research Question 5: How do frequency, duration, and intensity of physical activity and sedentary behaviors affect risk for obesity?

Research Question 6: Do transitions in characteristics of peers and peer behaviors and the quality of peer affiliations account for changes in physical activity and sedentary behavior after these transitions?

Research Question 7: What are the physical activity- and sedentary behavior-genetic interactions that affect the expression of genetic risk for obesity?

Research Question 8: Do patterns of physical activity, sedentary behavior, and sleep have a differential effect depending on the presence of genetic risk for obesity?

Research Question 9: Do limited neighborhood walkability and limited access to facilities and parks suitable for physical activity provide an obesogenic environment?

Research Question 10: Does the transition from high school mark a significant change in frequency, duration, intensity, and type of physical activity and sedentary behavior which have a corresponding effect on risk for obesity?

Research Question 11: To what extent are short-term changes in physical activity, sedentary behavior and sleep as a result of the transition out of high school maintained beyond the first year after high school?

Research Question 12: Does physical activity have a positive effect on subsequent peer relationships, family relationships, mental health, and quality of life?

Research Question 13: Does sedentary behavior have a negative effect on subsequent family and peer relationships, mental health, health risk behaviors, and quality of life?

Research Question 14: During adolescence, does time spent sleeping relate to obesity and to other health indicators including physical health and quality of life?

Research Question 15: Are the relations between sleep and obesity and other health indicators consistent across adolescence and early adulthood?

Substance Use:

Research Question 1: What are the developmental patterns of onset, experimentation, maintenance, and cessation of tobacco, alcohol, and marijuana use during high school and the transition out of high school? Do these patterns differ across substances?

Research Question 2: What are the determinants of the onset, maintenance, and cessation of binge drinking?

Research Question 3: What are the early predictors of problem drinking during the years after high school?

Research Question 4: How do family influences on adolescent substance use vary over the period of study, particularly as youth transition away from their family of origin to school or work environments? What patterns of family influence emerge and do these vary by adolescent's place of residence or school/work status, or interaction of the two?

Research Question 5: What are the relative contributions to substance use of adolescents selecting peers and entering peer groups that have similar substance use patterns to theirs (peer

selection) versus peer groups influencing the subsequent onset, maintenance, and cessation of substance use (peer influence)?

Research Question 6: Does the nature of peer influence vary over time and by substance?

Research Question 7: What are the behavior-genetic interactions that affect the expression of genetic risk for use of different substances?

Research Question 8: What are the influences of policies, neighborhoods, and other environmental factors on substance use over the period of study and how are these effects moderated by family and peer behaviors?

Driving Performance and Risk:

Research Question 1: What are adolescent perceptions of, and attitudes about, teen driving risk and how do they vary over time in relation to driving performance?

Research Question 2: How important are social influences on driving behavior and under what conditions do these influences operate?

Research Question 3: What is the prevalence of safety belt use, risky driving behavior, moving violations, and crashes and how do these vary over time and by population characteristics (e.g., gender, race)?

Research Question 4: How do patterns of adolescent substance use, substance use while driving and exposure to drivers using substances relate to adolescent driving performance?

Research Question 5: What is the effect of sleep patterns on risky driving behavior, moving violations, and crashes and how do these vary over time and by population characteristics (e.g., gender, race)?

Research Question 6: What is the effect of environmental factors, such as the availability of

public transportation, bike paths, and other vehicle options on driving exposure and outcomes?

Dating Violence:

Research Question 1: What is the prevalence of physical violence, sexual violence, threat of physical or sexual violence, and psychological or emotional abuse in dating relationships of a nationally representative sample of adolescents ages 16 through 22?

Research Question 2: How does the incidence and prevalence of dating violence change with age within different gender and race/ethnicity groups?

Research Question 3: What is the stability of dating violence perpetration and victimization within individuals?

Research Question 4: What characteristics of romantic relationships are associated with dating violence?

Research Question 5: What are the individual, family, and contextual precursors to dating violence perpetration and victimization?

Research Question 6: What is the (complex) relationship between other adolescent health behaviors, risk behaviors (such as substance use), mental health problems and dating violence? Are these behaviors and health indicators products of dating violence, precursors to dating violence or concurrent facilitators of dating violence?

Research Question 7: Do changes in physical violence, sexual violence, threat of physical or sexual violence, and psychological or emotional abuse in dating relationships of young adults occur when there is a significant change in the characteristics of close friends?

A3. Use of Information Technology and Burden Reduction

As required in 5 CRF 1320.5 (d2), the investigators researched technological advances in data collection that might reduce participants' response burden. A web-based survey is used as the primary mechanism for both the annual and peer surveys. For those participants who do not have access to a computer or high-speed internet service, a hard copy is used as the backup procedure. Most of the data required for the NEXT Generation Health Study cannot be accessed from currently existing automated databases to reduce the collection burden. However, where possible, existing automated databases is linked to NEXT data to supplement survey and other NEXT procedures. For example, geocodes of participant home, school and work addresses are linked to existing databases characterizing the neighborhoods. During questionnaire design, every effort has been made to limit respondent burden. The time required to complete the annual online questionnaire is approximately 60 minutes. The time required to complete the online peer questionnaire will be approximately 40 minutes.

The Information Technology System Security Plan provided in Attachment 8 describes the policies, procedures and controls by which Abt SRBI Inc. protects participant data collected through online surveys. This plan was developed in accordance with the standards put forth in the National Institute of Standards and Technology (NIST) Special Publications 800-18, *Guide for Developing Security Plans for Information Technology Systems*, 800-12, *An Introduction to Computer Security: The NIST Handbook*, and, 800-14, *Generally Accepted Principals and Practices for Securing Information Technology Systems*.

To obtain accurate estimates of daily caloric intake, proportion of calories from fat, carbohydrates, and protein, or whether daily intake meets dietary guidelines, participants complete an online dietary questionnaire, called ASA24, in each year of the study. Participants

complete the online 24-hour dietary recall, for three days (two weekdays and one weekend day) each year. The ASA24 was recently upgraded by NCI and has been shown to have good reliability and validity for assessment of all nutrient groups. Utilizing an online diet recall method allows participants to submit this information at a time that is convenient for them, thereby reducing burden.

In order to collect accurate physical activity and sleep information, NEXT Plus participants wear an accelerometer all day for 7 days and an ActiWatch® all day and night for 7 days during each year of the study. The accelerometer and the ActiWatch® capture data on the frequency, duration, and intensity of bouts of physical activity for each participant without requiring direct input from the participant. Participants concurrently keep a written 3-day activity diary, which is submitted for data coding and analysis immediately following the 7-day period in which they wear each device.

A4. Efforts to Identify Duplication and Use of Similar Information

Efforts to identify duplication consisted of extensive literature reviews and consultation with experts in epidemiology, survey research, and other Federal agencies. Unlike cross-sectional surveys in the United States such as the Youth Risk Behavior Survey (YRBS; OMB No.: 0920-0493, exp. date: 11/30/2011) and National Health and Nutrition Examination Survey (NHANES; OMB No.: 0920-0237, exp. date: 11/30/2012), NEXT examines longitudinal determinants of health behavior, including family, school and community influences on health behavior. Both NHANES and YRBS have smaller age-specific sample sizes. Add Health (<http://www.cpc.unc.edu/projects/addhealth>), a longitudinal study of adolescents begun in 1994-95, is not currently collecting data on adolescents. A cause and effect relationship cannot be

determined in cross-sectional studies and such studies are also limited in their ability to infer developmental changes in health behaviors. There are no national longitudinal studies of cardiovascular risk factors covering this developmental period. The NEXT Generation Health Study also surveyed school administrators to provide information about school and community context and also collects data on family environment. This study does not duplicate the NICHD National Children's Study (NCS) that is studying the influence of genetics and environmental toxins on children's health from birth through 21 years. Data collection for that study is at its infancy and begins with pregnant women.

A5. Impact on Small Business or Other Small Entities

This information collection does not apply to small businesses or other small entities.

A6. Consequences of Collecting the Information Less Frequently

Collecting the data less frequently undermines the ability to examine the immediate effect of changes in health behavior determinants and the effect on corresponding health behaviors and health outcomes. A one-year time frame between assessments is needed because this is a period of rapid change in diet, physical activity, substance use (including the onset of binge drinking), dating and dating violence, and the onset of licensure for driving. For example, one of the limitations of the Add Health longitudinal study is that it was not possible to examine short-term changes in peers and peer groups and their effect on adolescent risk behaviors. Collecting data annually for seven years also provides sufficient data for sophisticated analyses of links between changes in the trajectories of health behavior determinants, health behaviors, and health status. One of the strengths of this study will be examining changes after the transition out of high school. The repeated measures both prior to and after this transition

enables investigators to identify patterns of behavior during the high school year that put adolescents at risk after they have left home and are living on their own. The sophisticated analyses described in the analysis section would not be possible without repeated annual assessments.

A7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

This research study fully complies with 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The 60-day Federal Register Notice was published on February 23, 2012 (Volume 77, Number 36, Pages 10758-10759). No public comments were received in response to the Notice.

Consultations for this research project have been obtained incrementally since its inception. The most recent consultations occurred between January 2011 and February 2012. The initial concept and subsequent proposal were reviewed by two different External expert panels who evaluated the justification, design, and methods of the study. NICHD obtained external statistical review of five proposals for both methods and sample designs. The protocol, methods and assessments were also reviewed by the NICHD Director of Intramural Research and a panel of independent extramural investigators selected by the Director. During its evaluation of the proposal, the NICHD IRB commented that they had never seen such positive reviews by external experts. For example, one external reviewer wrote: “Proposal is outstanding. This study will generate a rich database far and above the CDC Youth Risk Behavior Survey.”

Another external reviewer commented: “This study offers the potential of better understanding the foundation and interaction of some of the key public health issues of adolescents and the future health of our society... Well thought out and comprehensive design...Very exciting study! Should be a major contribution.” Several levels of review and evaluation have been completed by participating institutes (NHLBI, NIAAA, NIDA) including reviews by experts both internal and external to the National Institutes of Health. For example, in the review by the NHLBI Board of External Experts, the approval was near unanimous (with one dissenting voter requested screening for carotid intima-media thickness which has subsequently been added in this application for continuation of the study).

In addition, the questionnaire was distributed for review, comment, and endorsement to representatives of the broader education and health promotion community at the national, state, and local education agencies and those involved in the health and welfare of children. These consultations included 31 representatives of state, local, and national education agencies.

A9. Explanation of Any Payment or Gift to Respondents

Methodological studies of health assessments have indicated the importance of individual incentives for recruiting and maintaining a representative sample and for reimbursing participants for time spent completing study requirements (Martinson et al., 2000; Morrison et al., 1997; Drews et al., 2009). This will be particularly important as all participants are now potentially wage-earning adults. The proposed incentive plan received high praise at various levels of the review process, was cited as a strength of the proposal by external reviewers, and received unanimous support by the NICHD Institutional Review Board which review study ethics to protect human subjects.

The overall incentive structure for the annual survey is presented below:

Year of Participation	Completing Survey
Wave 4	\$40 gift card
Wave 5	\$45 gift card
Wave 6	\$50 gift card
Wave 7	\$55 gift card
Overall Total	\$190 value

With regard to the peer surveys conducted in 2013 and 2015, NEXT Plus participants will receive \$25 for each friend they successfully recruit. Friends will receive an incentive of \$25 for completing the survey.

A10. Assurance of Confidentiality Provided to Respondents

All possible precautions are taken to ensure the privacy of individuals responding to surveys and other modes of data collection. Individual respondents are identified only by project-specific identification numbers. All study data are sent by the data collectors by overnight delivery to the home office data entry staff right after they are collected and then entered or scanned into a password-protected computerized data file and stored for analysis. Locking file cabinets are used to hold all paper copies containing information that may be used to identify study participants. Access to such information is controlled by individual project directors, who provide access to information only to selected project staff who are actively working with the data. Precautions are taken to ensure the privacy of individuals responding to surveys and other modes of data collection, including keeping names and addresses separate from completed instruments, and using only identification numbers. Personal identifying information is collected separately from the surveys or other instruments in order to track the participants over time (for annual assessments). These data are maintained in a separate (tracking) database which is password protected and encrypted. A certificate of confidentiality

has been obtained to protect against requests for personal data (see Attachment 9). The protocol and survey has been approved by the NICHD Institutional Review Board (IRB).

Procedures for obtaining consent are consistent with those of other U.S. national studies. Due to the longitudinal nature of NEXT and nature of the tasks involved, active parental consent was required before participants turned 18 and all participants provided active consent after their 18th birthday. Participants are informed in writing that they may skip any or all questions or refuse to participate in the survey and that they have the opportunity to not participate in the study. Each questionnaire has a unique code to facilitate accurate scanning of responses into the appropriate record of a database. Participants are sent an email with a link to the online survey. In a separate communication a login and password is provided to access the survey. If participants require a hard copy, they are instructed *not* to put their names on the survey. Upon completion of the survey, participants are directed to insert their booklets into postage-paid FedEx envelopes and either drop them in a local FedEx box or contact the study center to have them arrange for a FedEx pickup at their home, school, or place of work.

During data processing, all completed questionnaires, data collection forms, and electronic data are stored in locked files at the contractor's offices and are accessible only to staff directly involved in the project. All members of the project are required to sign a statement of personal commitment to guard the confidentiality of data.

A11. Justification for Sensitive Questions

Some of the questions on the NEXT questionnaire might be considered to cover slightly sensitive topics. Depending on the participant and the setting, nearly any question about health behavior, dating violence, and use of alcohol or tobacco could be considered sensitive. The

behaviors covered in the survey are among the major behaviors known to increase mortality and morbidity, and multiple NICHD/PRB, NHLBI, NIAAA, NIDA and HRSA/MCHB programs address these behaviors. In order to examine determinants of behavior, it is essential to gather detailed demographic information about the respondent, including limited data on their socioeconomics.

The core NEXT questions were developed from HBSC and other surveys which have previously received approval from OMB and/or have been used already in the U.S. and other nations, and are presented in a straightforward manner. Supplementary measures were developed specifically to meet the program needs of NICHD, NHLBI, NIAAA, NIDA and HRSA, and other Federal agencies and have been administered in previous rounds of HBSC and other US surveys approved by OMB. These were developed in consultation with other agencies and national organizations such as the American School Health Association and the National Association of School Health Nurses. The criteria for selection of items included that there is published data on reliability and validity.

Personal identifying information is collected separately from the surveys or other instruments in order to track the participants over time (for annual assessments). These data are maintained in a separate (tracking) database which is password protected and encrypted. Since NEXT collects potentially sensitive data from adolescent subjects, confidentiality of data collected is essential, both to protect the right of participants' privacy and to assure honest reporting.

A12. Estimates of Hour Burden Including Annualized Hourly Costs

The NEXT survey addresses a sample of health-related factors according to rigorous

research protocols. The nationally representative cohort of U.S. youth has completed three Waves of data collection. We are requesting approval to continue these assessments for four more waves, through 2016. The estimates provided in Tables A. 12-1 and A. 12-2 below are for the maximum number of young adults that may be surveyed assuming a 95% response rate in the maximum number of eligible members of the cohort. The table also assumes that the average NEXT Plus participants will recruit five friends (six is the maximum number permitted) to complete the peer survey. The administrative requirements and completion of the annual online survey take approximately 60 min. Peer surveys are estimated to take 40 min.

Table A.12-1 Annual Burden for Affected Public: Young Adults in the NEXT Cohort and The NEXT Plus Nominated Peers .

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses Per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Young Adults in NEXT Cohort	2,100	1	1.0	2,100
Peers Recruited by NEXT Plus Young Adults	2,535	1	40/60	1,690

The estimated annualized cost to respondents for the 2013 (Wave 4) surveys is \$31,942 (Table 12-2). This estimate was calculated using 2011 Department of Labor figures for average wages in the US (however, NEXT participants will be first-year workers and probably make less) and US Department of Labor data that 68.3% of high school graduates attend college. That is, 68.3% of participants in 2013 will not be wage earners in the labor force so only 31.7% will contribute to the cost of the surveys in 2013 (Wave 4). The average costs for Waves 5 and 7 will

be less because these years will not include the peer survey (third row of Table A. 12-2).

Table A.12-2 Annual Cost to Respondents – 2013 Surveys Only.

Type of Respondents	Estimated Total Annual Burden Hours Requested	Estimated Annual Earnings During Survey Based on US Statistics	Average Hourly Earnings (with rounding)	Estimated Cost During the 2013 Survey Year
Young Adults in NEXT Cohort	2,100	\$45,230	\$21.74	\$14,472
Peers Recruited by NEXT Plus Young Adults	2,535	\$45,230	\$21.74	\$17,470

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

No direct costs to the respondents themselves are anticipated.

A13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to the respondents.

A14. Annualized Cost to the Federal Government

The survey is funded by a contract award to The CDM Group, Inc. at \$6,961,825 for 2013 through 2016. Thus, the annualized contract cost is \$1,740,456. These costs cover the following activities:

- Designing and planning the survey administration procedures
- Maintaining web-based systems for collecting surveys from participants
- Pilot testing the questionnaires
- Annual collection of all data from over 2,000 cohort participants
- Maintaining the study cohort

- Recruiting over 2,500 friends of NEXT Plus participants
- Collecting survey data from over 2,500 friends of NEXT Plus participants
- Recruiting and training field staff
- Collecting and processing data
- Weighting and cleaning of data
- Developing a data file with documentation
- Assisting in dissemination and reporting of results.

Additional costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of the survey and conduct of data analysis. It is estimated that ten NICHD/PRB, NHLBI, NIAAA, NIDA and HRSA/MCHB employees will be involved at the following rates and time allocation at 2,040 hours per year:

- Approximately 10% of time for the principal investigator at a salary of \$100 per hour.
- An average of 20% of time for nine investigators, staff scientists, post-doctoral investigators, interns, and analysts at average salaries of \$38 per hour.

Direct costs in NICHD/PRB, NHLBI, NIAAA, NIDA and HRSA/MCHB support staff time will be approximate \$127,504 annually. Therefore, the annualized cost to the government will be $\$1,740,456 + \$163,072 = \$1,903,528$.

A15. Explanation for Program Changes or Adjustments

This is a revision of an OMB approved longitudinal study. As explained above, the revision is the collection of survey data from friends of the primary participants. These data are essential for identifying social influences on the health, health behaviors, and health risk behaviors of the cohort being studied.

A16. Plans for Tabulation and Publication and Project Time Schedule

Plans for Tabulation. The contractor cleans and tabulates the results according to the cleaning, coding, and file requirements of the NICHD. After identifying information is deleted from the datasets, data files are subsequently made available for other investigators.

Publication Plans. The U.S. data results are made available promptly to the public through government publications, peer reviewed journal articles, and through the annual conferences of several relevant national and international organizations. The publications include analyses of the results and assessment of the implications of results for federal, school, and community-based programs. Published articles are sought in periodicals involved in health promotion, education, and other aspects of public health. Planned publications include the following:

- (1) Government publications such as “Results of the 2010-2013 NEXT Generation Health Study.” Publications will include collaborations between NICHD/PRB, NHLBI, NIAAA, and HRSA/MCHB describing the program and policy implications.
- (2) Analyses of behavioral research questions with pre- and postdoctoral students through collaborative mechanisms available at NICHD/PRB, NHLBI, NIAAA, NIDA, and HRSA such as the NIH Intramural Research Training program, and HRSA/MCHB.

Time Schedule for the Project. The following represents the proposed schedule of activities for NEXT, in terms of months after receipt of OMB clearance. The end date for data collection is constrained by funding requirements and programmatic need for these data. Data collection will occur from January 2013 through August 2016. Key project dates will occur during the following time periods:

<u>Activity</u>	<u>Time Period</u>
Collect data	January, 2013 through August, 2016
Process data	July, 2013 through December, 2016
Weight/clean data	July, 2013 through December, 2016
Produce data file	Decembers of 2013, 2014, 2015, and 2016
Analyze data	September, 2013 through August, 2017
Publish results	January, 2013 through January, 2018

Results are published in 2012 and periodically from 2013 through 2018, within the United States and internationally. As also noted in B.3 below, it is extremely important to continue data collection at the beginning of 2013. Previous annual assessments were in the Spring of 2010, 2011, and 2012. In order to maintain the design of the study which requires annual assessment approximately every 12 months, it is essential that approval be received in a timely manner for continuing data collection.

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

All forms will display the OMB expiration date.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are being requested. The certifications are included in the package.