Supporting Statement A for

NEXT Generation Health Study - NICHD

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A1. Circumstances of Making the Collection of Information Necessary

Justification for 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 collection of information to be completed between 2010 and 2013 in order to collect reliable and valid data on changes in health and health behavior in a cohort of U.S. adolescents. The study will collect information on adolescent health behaviors and social and environmental contexts for these behaviors annually for four years beginning in the 2009-2010 school year. Hispanic and African-American youth will be oversampled to provide better population estimates of these groups and to provide an adequate sample to examine racial/ethnic differences in longitudinal predictors of health, health behaviors, and health behavior change. Self-report of health status, health behaviors, and health attitudes will be collected by in-school and online surveys. Anthropometric data, genetic information, and neighborhood characteristics will be gathered on all participants as well. The study will also incorporate an Administrator Survey and other data sources to obtain related information on school-level health programs and community-level contextual data to support NICHD, the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Alcohol Abuse and Alcoholism (NIAAA), 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 will be identified: additional data on behavioral risk factors and biological markers and risk factors will be gathered on these adolescents. The purpose of this OMB application is to permit the collection of longitudinal health behavior and health status data in a cohort of U.S. adolescents over a period of four years.

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. 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. 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: 12/31/2011], National Health Interview Survey [NHIS; OMB No.: 0920-0214, exp. date: 12/31/2009], 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. 0930-0110, exp. date 01/31/2010]; 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, is a consortium of investigators from 40 European and North American countries who conduct a common survey of early adolescent health behaviors and psychological, social, and contextual influences on these health behaviors. HBSC is conducted every four years. The U.S. previously carried out HBSC surveys in 1997-1998, 2001-2002, and 2005-2006 and is conducting an HBSC survey in 2009-2010. The 1997/1998 HBSC survey was approved by OMB on December 12, 1997 (OMB #0925-0451, expired 12/31/00), the 2001/2002 HBSC survey was approved by OMB on October 3, 2001 (OMB #0915-0254, expired 10/31/04), the 2005/2006 survey was approved by OMB on January 17, 2006 (OMB #0925-0557, expired 01/31/09), and the 2009/2010 survey was approved as an extension by OMB on January 30, 2009 (OMB #0925-0557, expires 01/31/2012).

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. Add Health was also effective in examining broad changes in other adolescent risk behaviors and potential determinants but 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 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 biological and environmental factors in youth in light of many recent scientific advances in

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), an independent extension of the HBSC survey (OMB No.: 0925-0557, exp. date: 1/31/2012), will follow a cohort of 10th-grade students for four years. This cohort will be tracked through the post-high-school year, permitting a unique opportunity to examine predictors of changes in health behaviors and mental health during significant family and career/education transitions. A small group of other countries are also planning longitudinal studies using HBSC survey items. This increases the potential sample size for growth curve analyses and will permit cross-country comparisons of changes in health risk behaviors and the factors influencing these changes.

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 the Prevention Research Branch (PRB) of NICHD, NHLBI, NIAAA, and HRSA/MCHB. 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. HRSA/MCHB has the primary responsibility for promoting and improving the health of adolescents through program and policy; the 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, 2010, NICHD/PRB, and HRSA/MCHB. The foci of NICHD/PRB, NHLBI and NIAAA 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 being completed by the same staff as those conducting the already approved HBSC study (OMB No.: 0925-0557, exp. date: 1/31/2012). Staffing and training of this staff is coordinated between the two studies. Funding cycles also fix the dates for the survey to be completed during the 2009/2010 school year. Substantial testing and evaluation takes place in U.S. high schools during the second quarter of 2010. Delay in OMB approval could result in an increase in schools declining participation in the NEXT study because surveys will compete with this testing; this could result in a sample that is not

representative of U.S. adolescents. In order to coordinate the NEXT survey with the staffing of the HBSC study and to keep the study timeline synchronized with the corresponding HBSC survey (for example, permitting comparisons between the longitudinal sample and the HBSC cross-sectional sample), it is essential that the baseline NEXT survey be conducted during the first quarter of 2010. For these reasons, we are requesting OMB approval to begin survey administration on January 1, 2010.

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

A2. Purpose and Use of Information

Survey Objectives and Information to be Collected. The 2010-2013 U.S. NEXT longitudinal study will fill 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 overall goals of the longitudinal study are to:

1. Identify the trajectories of adolescent health behaviors, including healthful diet and physical activity, substance use, dating violence, and health status, including obesity, metabolic syndrome, and injuries due to motor vehicle crashes or dating violence, from adolescence through the post-high-school year
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, and social/environmental precursors to developmental changes in diet, physical activity, substance use, dating violence, risky driving, and other health risk factors.
5. Examine the role of social networks in obesity and substance use, 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 will be completed for a subsample of adolescents. These include:

- Objective assessment of physical activity, sedentary behavior, and sleep
- 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, and blood pressure
- Assessment of nutrient intake

During NEXT, each participating student will complete a total of four health surveys. The first survey will be conducted in-school (when the students are in grade 10) and the following three surveys will be completed once annually thereafter, either online or over the telephone. Students will answer similar questions across all four surveys to identify changes in their behaviors. The Student Survey is shown in Attachment 1. Height, weight, and waist circumference will be measured once annually in schools during grades 10, 11, and 12 by trained

health researchers. Also, during the grade 10 assessment, trained health researchers will collect saliva samples from those students with parental consent to collect genetic material to look for genetic markers of disease or health risks. Our consent form indicates that genetic data will be stored to measure these specific markers and provides parent and child with the ability to opt-out of having the child's genetic material collected.

We will not conduct a GWAS with the genetic samples. Instead we will look for specific genetic markers including those for obesity, cardiovascular disease, metabolic syndrome and substance use. Because this is a rapidly developing field, we plan to store the genetic material until the end of the study to permit assessment of the latest significant markers.

A subsample of consenting students will participate in a more extensive assessment of factors affecting cardiovascular health. In particular, this substudy will more closely examine: adolescent physical activity, sedentary behavior, and sleep patterns; adolescent diet and nutrient intake; as well as biological and genetic markers for obesity and cardiovascular disease. To accomplish this, students will perform a dietary recall on three separate days in each year of the study. They will be asked to wear an accelerometer and ActiWatch® for 7 days and concurrently complete a physical activity diary during years 1 through 4. As part of a battery of in-home assessments performed in years 1 and 4, substudy participants will undergo finger prick blood collection to perform blood analyses, have their height, weight, and waist circumference measured, and have their blood pressure measured. Parents/guardians will also be asked to complete an in-home survey.

To support HRSA/MCHB program and research data requirements, an Administrator Survey will be completed in year 1 by appropriate school personnel in the surveyed schools to

obtain information on health and physical activity programs and policies. The Administrator Survey is modeled on the 2000 School Health Education Profile Survey (SHEPS) that is used in many states and coordinated through the Centers for Disease Control and Prevention (CDC), Division of Adolescent and School Health and the Health Behaviors in School-age Children Survey (HBSC; OMB No.: 0925-0557, exp. date: 1/31/2012). Extreme care will be taken to exclude the possibility of identification of schools or communities due to the Administrator Survey. Principals are asked to identify the most appropriate person on their staff who can respond to questions about the school's health programs and curriculum. That individual is then contacted during data collection and asked to complete the survey. If the Principal determines that he/she is the best possible respondent the School Administrator Survey is completed by him/her. The Administrator Survey for school principals or their designated alternates is shown in Attachment 2.

Linkage of school and community level information will be included to provide data from school and census level databases, such as the Quality Education Data (QED) and the Department of Education Common Core Data (CCD). These data will assist in measuring the social context in which the students function. For example, data would include the percent of students receiving subsidized school lunches, census tract poverty level for school location, school size, nutrition programs in schools, physical education requirements, violence prevention programs, etc. All of these factors are associated with the leading health indicators of the U.S. Healthy People 2010, making NEXT extremely relevant for the requirement that U.S. program and policy should be guided by appropriate research and measurable objectives. These are of the same research goals as those maintained by NICHD/PRB, NHLBI, NIAAA, and the same

program goals held by HRSA/MCHB. Budget has been obligated beginning in FY2009 from the NICHD/PRB and, through an Intra-Agency Agreement, from HRSA/MCHB and NIAAA to cover the cost of performing the study to assist in meeting their program needs. NHLBI funding of NEXT will begin in FY10.

Receipt and Distribution of Data. The data will be collected, merged, and cleaned by The CDM Group and Abt Associates. These organizations will deliver a final data set following each wave of data collection to NICHD/PRB for review and approval. CDM and Abt are also responsible for development and documentation of a public use data set to be approved and distributed by NICHD/PRB. NICHD/PRB will deliver the final data set to the collaborating agencies: NHLBI, NIAAA, and HRSA/MCHB. NICHD/PRB also will be responsible for coordination of use of the data by other Federal agencies and non-governmental organizations for use such as those described below.

Inter-Agency and Private Sector Use. The NEXT survey 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 in Years 1 and 4 in conjunction 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. This is a new data collection.

Evaluation Components**.** The evaluation will be 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, and HRSA/MCHB scientific and post-doctoral personnel.

Appropriateness and adequacy of sample, data collection, and analysis plans. The objective of NEXT is to conduct a longitudinal study of a nationally representative probability sample of students in grade 10 from public and private schools having estimates of population percentages with a margin of error of plus or minus 3 percentage points at the 95% confidence level. An oversample of minority children (African American and Hispanic) in grade 10 is also included in order to improve the validity of sub-group analyses and to better study health disparities. The objective is to construct a sampling frame that is current, complete, and accurate with respect to information needed for selection and stratification. The target population for the NEXT study is all 10^{th}-grade students in public, private, and parochial schools in the 50 states and the District of Columbia. For sampling students from public schools, primary sampling units (PSUs), which are either individual school districts or groups of school districts will be created and selected as a sample of PSUs at the first stage. A data file that identifies and

provides extensive data on school districts and individual schools has been purchased from The Quality Educational Data, Inc. (QED) and examined to construct a sampling frame of PSUs. The QED files are current and contain data on primary and secondary public schools as well as private and parochial schools. Private and parochial schools will be linked to public districts to ensure that these sampled schools will fall within the same sample clusters as sampled public schools.

A primary sampling unit (PSU) is either an individual school district or a group of school districts in adjacent counties. These were created using a population of around 14,000 school districts. At the first stage of sampling, a sample of primary sampling units was selected. The list of schools offering grade 10 was obtained for only the selected primary sampling units. There is no sampling of school districts within a selected PSU as the list of schools is formed based on all the schools in the PSU without regard to school district. From this list, a sample of schools was selected. Only after the selection of the school, the school district is identified for purposes of contacting the school. This method of sampling reduces the cost of data collection as the sample of schools is not spread very widely across the U.S. Also, if we want to directly sample schools from a list of schools, we need a complete sampling frame of schools which is a list of all schools in the U.S. offering grade 10 where in a multi-stage design we need the list only for selected school districts. It would be more expensive to get a complete and correct list of schools offering grade 10 than just restricting the list to selected PSUs.

For determining the sample size at the initial wave, a recruiting or retention rate of 80% at each wave (conservative compared to the previous work by us and others) is assumed as well as a response rate of 95% (conservative or consistent with previous work by us and others) from

those students who are successfully recruited or retained in the sample at each wave. The required sample size at the end of wave 4 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 of characteristics of interest between two time periods (for example year 3 and year 4) with 80% power when actually there is a difference of 5.3 percentage points with a two-sided statistical test at 5% of level of significance. For the determination of the sample size we assumed that the correlation between two time periods was around 0.5. The sample was first determined assuming a simple random sample of students. This gives a sample of around 700 students. Since the sample is selected using a multi-stage sampling design, we assumed a design effect of 1.5 based on previous HBSC surveys and 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 4 based on a sample size of 700 (or 1,050 with correction for the design effect) is plus or minus 3.7 percentage points.

The strategy for minority oversampling was based on the requirement of around 215 African-American students at the end of wave 4 out of sample of 1,050 completes. We expect to get around 180 African American students at the end of wave 4. Therefore, there is insufficient sampling of minorities in the basic sample. To get the additional minority students, we plan to identify school with a high percentage of African American students and select additional samples of students to screen and identify minority students. Originally it was planned to select additional primary sampling units for sampling Hispanic students. This plan is no longer necessary. We expect to get the required number of 215 Hispanic students without oversampling

as the percentage of Hispanic students is slightly higher than African-American students.

A conservative estimate of number of completes at each wave is shown in Table 1

Table 1: Expected Number of Completes at Each Wave

Wave	Completes		Total
	Main Sample	Oversample	
Wave 1	2,392	328	2,720
Wave 2	1,818	249	2,067
Wave 3	1,381	189	1,570
Wave 4	1,050	144	1,194

The sample is selected from the population of students in grade 10. Based on the assumed retention and response rates, 3,150 students need to be selected in the main sample and 430 students need to be selected in the oversample at baseline for a total of 3,580 students in grade 10. This sample is selected both from public and private schools. The sampling frame for the substudy will be all schools successfully recruited to participate in the basic survey. Seven overweight children and seven normal weight children will be randomly selected across classes from 54 schools and recruited to the substudy. See respondent universe and statistical sampling plan for the NEXT Generation Health Study in Section B.

For specific hypotheses using data from the substudy, the subsample of the longitudinal sample 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, 2000). 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 student physical activity and peer physical activity, i.e., a linear model with four 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 four outcome measures were set at 1 and to the slopes were set from 0 to 4 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 = 550 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 subgroup 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 should be higher in the in-home assessment than the in-school sample because they will have already completed the Year 1 in-school assessment and will have consented to the additional in-home assessment. To assure a final sample size of 550 we will start with a sample of 750 in Year 1. The larger sample participating in the survey but not the home visits would provide 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 expects the initial wave of data collection to occur in the spring of 2010 (January-June) depending on individual school schedules and availability. A general schedule of data collection is provided below:

	Grade 10	**Grade 11**	**Grade 12**	**Post-high school**
Survey	Spring 2010 (in-school)	Spring 2011 (online or computer-assisted telephone interview)	Spring 2012 (online or computer-assisted telephone interview)	Spring 2013 (online or computer-assisted telephone interview)
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)			
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)	Spring-Summer 2013 (7-day monitoring)
Dietary Recall† (3-day diet recall)	Spring-Summer 2010 (online)	Spring-Summer 2011 (online)	Spring-Summer 2012 (online)	Spring-Summer 2013 (online)
Blood Analyses† (finger prick blood collection)	Spring 2010 (in-school)			Spring 2013 (in-home)
In-home Assessments† (height, weight, waist circumference, blood pressure, in-home survey)	Spring-Summer 2010 (in-home)			Spring-Summer 2013 (in-home)

† - Data collected from substudy participants ONLY

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, will be expected to complete: final piloting of the survey, anthropometric assessment techniques, and saliva sample collection techniques; collection of annual data from NEXT and substudy participants; and completion of the final datasets by the required deadlines.

Analytic approach. Analyses will proceed from preliminary assessment 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 2010-2013 U.S. NEXT longitudinal study will fill 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:

1. Identify the trajectories of adolescent health behaviors, including healthful diet and physical activity, substance use, dating violence, and health status, including obesity, metabolic syndrome, and injuries due to motor vehicle crashes or dating violence, from adolescence through the post-high-school year
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, and social/environmental precursors to developmental changes in diet, physical activity, substance use, dating violence, risky driving, and other health risk factors.
5. Examine the role of social networks in obesity and substance use, 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 will be 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 will be considered at this point**.**

Descriptive statistics for relevant groupings, for example, race, sex, gender, and age, will be obtained. Typically, logistic and ordinary least squares (OLS) regression analyses will be 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 will be 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 will be 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. At least 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. For some analyses, the 3 anthropometric assessments will be sufficient. In addition, we will gather self-reported heights and weights at four points in time and will be able to use the combination of self-report and measured heights and weights to impute more accurate estimates at the fourth point in time should it be necessary. In the subsample we will have measured height and weight at four points in time. These values will also contribute to the imputation equations.

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 will be employed to ensure that imputation of missing data is appropriately handled. In general, random missing data will 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: Does an obesogenic diet include significantly higher consumption of saturated and trans fats, soda, and fried foods?

Research Question 2: Does an obesogenic diet include significantly lower consumption of fruits and vegetables?

Research Question 3: Does an obesogenic diet include significantly higher consumption of carbohydrates with a high glycemic index which also relates to blood glucose levels?

Research Question 4: Do changes in dietary composition precede corresponding changes in body composition and blood glucose levels?

Research Question 5: What are the diet-genetic interactions that affect the expression of genetic risk for obesity?

Research Question 6: Does neighborhood access to fast food outlets provide an obesogenic environment while access to fresh food markets reduces this effect?

Research Question 7: Does regular consumption of breakfast reduce risk for obesity?

Research Question 8: Does family eating patterns (e.g., eating together at primary meals, TV watching during meals) affect risk for obesity?

Research Question 9: Does the transition from high school to the first year after 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?

<u>Physical Activity:</u>

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

Research Question 6: How do frequency, duration, and intensity of physical activity affect risk for obesity?

Research Question 7: How do frequency, duration, and type of sedentary behavior affect risk for obesity?

Research Question 8: Is time spent with peers related to increased physical activity or increased sedentary behavior?

Research Question 9: What are the physical activity- and sedentary-behavior-genetic interactions that affect the expression of genetic risk for obesity?

Research Question 10: Does the transition from high school to the first year after 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: Does physical activity have a positive effect on subsequent peer relationships, family relationships, mental health, and quality of life.

Research Question 12: Does sedentary behavior have a negative effect on subsequent family relationships, mental health, health risk behaviors, and quality of life.

Research Question 13: During adolescence, does time spent sleeping relate to obesity and to other health indicators including physical health and quality of life?

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 year after high school?

Research Question 4: How do family and peer influences on adolescent substance use vary over the period of study?

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: Do the relations of substance use with the different aspects of peer relationships being assessed differ for different substances (described in Research Question 4)?

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 (school policies captured in the administrator survey as well as the policies of local communities which are available in existing

databases), 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: 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 5: 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 15 through 19?

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 are the individual, family, and contextual precursors to dating violence perpetration and victimization?

Research Question 5: 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?

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. For the initial survey, a school-based survey is more efficient than implementing a web-based survey or computer-assisted telephone interviews (CATI) to identify the needed student samples. The NEXT Generation Health Study will employ the same survey response technology employed in the schools for other standardized tests. Specifically, the students will report their survey responses on data forms, marking the appropriate spaces with pencil marks that can be scanned for data entry directly into files. This procedure is standard in school-based surveys and is a simple, convenient, and preferred way for students to record their responses. The data required for the NEXT Generation Health Study cannot be accessed from currently existing automated databases to reduce the collection burden. During questionnaire design, every effort has been made to limit respondent burden. The time required to fill out the questionnaire will be 40 minutes or one class period.

While the initial student data collection is most efficient when implemented in the classrooms, web-based survey techniques will be used in two areas. Students who are absent from school on the day of the survey administration will be asked to complete the survey online (in private; in school; during the school day), improving the staffing efficiency. Additionally, follow-up surveys to be completed annually for three years after the initial in-school survey will utilize online survey methods or CATI, allowing students to complete the survey at a time that is convenient for them.

The Information Technology System Security Plan provided in Attachment 17 describes the policies, procedures and controls by which Abt SRBI Inc. will protect student 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, students will complete an online dietary questionnaire, called ASA24, in each year of the study. Students will complete the online 24-hour dietary recall, for three days (two weekdays and one weekend day) each year. The ASA24 was recently developed 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 students 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, students will 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® will capture data on the frequency, duration, and intensity of bouts of physical activity for each student without requiring direct input from the student. Students will concurrently keep a written activity diary, which will be 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: 12/31/2011), 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 potential involvement of other countries in this project is unique; the HBSC international collaboration provides an opportunity to not only make cross-national comparisons but to look for international patterns that could provide valuable insights into potential causes of CVD and the obesity epidemic. The NEXT Generation Health Study also surveys 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 four 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 prior to this transition will enable 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 June 17, 2009 (Volume 74, Number 136). Two public comments were received. One questioned the value of this study and suggested that the study could not possibly be completed within the stated cost estimates. We have always conducted extremely efficient studies within stated cost estimates. The value of this research is demonstrated by the involvement of multiple government agencies. The second email simply expressed interest in more information.

Consultations for this research project have been obtained incrementally since its inception. The most recent consultations for this 2009/2010 survey occurred between October 2007 and June 2009. 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 (NHBLI, NIAAA) 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 requesting additional measures of sub-clinical indicators which would have required complex and expensive procedures which would have substantially increased respondent burden).

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. <u>Explanation of Any Payment or Gift to Respondents</u>

In the past, OMB has been concerned about being able to recruit a representative sample of schools and, recognizing that it is not an educational survey, have encouraged us to increase our incentives to assure better recruitment and to recognize the burden being placed on schools

resources. In the OMB-approved cross-sectional HBSC study, we are providing a school incentive of $500. Schools assist in distributing and collecting information about the study and consent forms. They provide updated information about classes and participants for sampling. They coordinate survey dates and times with us and arrange for appropriate in-school locations for survey administration. They complete a school-level ('Administrator') survey. They accommodate our health survey procedures. And they assist with scheduling follow-up health surveys for absentees. The schools in the proposed study are being asked to do more than the HBSC study. In addition to the in-school health survey, they will accommodate two medical assessments: in coordination with our staff, they will provide space suitable for the anthropometric measures and collection of genetic material for all participating students; on a separate day, they will provide space for us to collect fasting blood samples and to provide breakfast to participants. In the following two years, schools will be asked to coordinate repeated anthropometric assessments of the participating students. Because the proposed study is longitudinal and more extensive than HBSC, the schools are being asked to make a greater, long-term commitment. Among the best-known government-funded longitudinal studies of adolescent health, i.e. AddHealth beginning in 1992, provided an incentive of $1,000 to schools in the first year. A more recent government-funded study of adolescent health (HEALTHY, Drews et al., 2009) provided $2,000 to control schools in year 1, $4,000 in year 2 and $6,000 in year 3.

Methodological studies of health assessments have indicated the importance of individual incentives for recruiting and maintaining a representative sample. With regard to initial recruitment in a health study, Martinson et al. (2000) found that a higher incentive ($15) resulted

in significantly better recruitment than a low ($2) or no incentive. In the early 1990s, AddHealth provided $10 for completing surveys outside of school and $20 for each anthropometric assessment. Methodological analyses regarding maintaining samples of adolescents participating in longitudinal studies of health (Morrison et al., 1997; Drews et al., 2009) indicate the importance of incentives for maintaining a representative sample. They also suggest that lotteries might be effective for subject maintenance in longitudinal studies (accumulating greater chance of winning with increased number of responses).

Based on prior recommendations from OMB encouraging the government to consider payments to schools to increase the school participation rate on the national YRBS (Larkin et al, 2002), NICHD/PRB and HRSA/MCHB has determined that the use of incentives is necessary to encourage school and student participation and improve response rates. Thus, NICHD/PRB originally proposed offering monetary incentives to participating schools, staff, and students in the amounts depicted below, which are comparable or less than other health-related studies doing similar in-school anthropomorphic and biological assessments (e.g., The HEALTHY Study Group, in press). 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 human subject ethics review board. However, in response to the recommendations of OMB reviewers, this plan has subsequently been revised.

SCHOOLS

	Schools
Grade 10	**$500**
Grade 11	**$250**
Grade 12	**$250**

STUDENTS

Year of Participation	**Completing Survey**	**Completing Weight, Height, and Waist Circumference Measurements (and Saliva Sample in Year 1)**	**Total by Year**
10th grade	none	$ 10	$10
11th grade	$ 10	$ 10	$20
12th grade	$ 10	$ 10	$20
After high school	$ 10	No measurement conducted	$10
Overall Total	$ 30	$ 30	$60

SUBSTUDY STUDENTS

Year of Participation	**Completing home visit (height, weight, blood pressure, waist circumference) and home surveys**	**Completing dietary questionnaire for three days**	**Wearing accelerometer and ActiWatch® for all seven days**	**Completing daily activity diary for all seven days**	**Fasting blood draw**	**Total by Year**
10th grade	$10	$10/day	$25	$25	$10	$100
11th grade	No visit	$10/day	$25	$25	none	$80
12th grade	No visit	$10/day	$25	$25	none	$80
After high school	$10	$10/day	$25	$25	$10	$100
Overall Total	$20	$120 for 12	$100	$100	$20	$360

Year of Participation	Completing home visit (height, weight, blood pressure, waist circumference) and home surveys	Completing dietary questionnaire for three days	Wearing accelerometer and ActiWatch® for all seven days	Completing daily activity diary for all seven days	Fasting blood draw	Total by Year
		days				

A10. <u>Assurance of Confidentiality Provided to Respondents</u>

All possible precautions will be taken to ensure the privacy of individuals responding to surveys and other modes of data collection. Individual respondents will be identified only by project-specific identification numbers. All study data will be sent by the data collectors by overnight delivery to the home office data entry staff right after it is 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 will be 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 will be obtained to protect against requests for personal data. 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 will be required. To accomplish this, parents will be provided with a letter from the school principal introducing the survey, a color brochure describing the study, and the consent form requesting permission for their children to participate. The cover letter describes all elements of the study and informs them that their children's participation is voluntary. The cover letter will assure parents that if they decide their children should not participate in the study, that decision will not affect their children's grades in any class. Parents will also be asked to review the form with their child as well as the child assent form and have their child sign the assent form if they agree to participate.

Project staff will work with the school principals to construct, distribute, and collect the letters. The consent forms and letters will be sent home with students and classroom teachers will be instructed to encourage students to return the consent forms as quickly as possible. Returns will be monitored by the School Survey Liaisons (SSL), i.e., teachers or school administrators who will be "hired" at each school recruited to the study. For parents who have not returned signed consent forms within three days, a second consent form and letter will be sent home with the student, reminding the parent of the study and requesting that they return the form. This process will be repeated for parents who have still not returned the form after one week. Students will be informed verbally and in writing that they may skip any or all questions or refuse to participate in the survey, the anthropometric measures, or the saliva sample collection, in which case an alternative activity approved by the school administration will be provided.

Students will be reminded that they have the opportunity to not participate in the study. All selected schools, students, and their parents will be informed that though information will not be anonymous, confidentiality will be maintained because only identification numbers (separately linked to personal information) will be used on questionnaires and data collection forms and privacy measures will be maintained throughout data collection. Additionally, all data will be safeguarded closely and no institutional or individual identifiers will be used in study reports.

The survey will be administered in a classroom setting, with adequate space between respondents. At the start of each survey, students will be told of the importance of the survey and how it will not be possible to identify their responses. They also will be reminded that they have the right to not answer any individual questions or to not participate in the survey if they are uncomfortable. Each questionnaire will have a unique code to facilitate accurate scanning of responses into the appropriate record of a database, Students will be instructed *not* to put their names on the survey booklets. Upon completion of the survey, students will be directed to insert their booklets into envelopes, seal the envelopes, and slip them into a sealed box with an opening just large enough to receive the booklet. The survey administrator will be required to seal and return the box for data processing as soon as possible after the administration of the survey, but no later than the next business day. Follow-up surveys will be completed using online survey methods or computer-assisted telephone interviews. Participants will be sent an email with a link to the online survey. In a separate communication a login and password will be provided to access the survey. Participants who do not access the online survey will be contacted by telephone and given the opportunity to complete the survey over the telephone.

For collection of anthropometric measurements, assessments will take place in private rooms supplied by the school or, when such rooms are not available, in private areas created with privacy screens in larger spaces when they are not in use (e.g., lunchroom, gymnasium). Separate stations will be created to measure height, weight, and waist circumference using standard protocols (Attachments 11 and 12) (e.g., The HEALTHY Study Group, in press; Pratt et al., 2008).

Saliva and blood samples will be sent to central laboratories where blood chemistry will be assayed and the DNA will be extracted, amplified, and sent to the NICHD repository for storage until subsequent analyses are conducted. Samples are identified by study number only, in a storage system separate from the name-address file of the participant in the study. Labs performing these analyses will only have these identification numbers. Only the Principal Investigator and Project Director (or designated assistants) have need and access to cross-reference the files.

During data processing, all completed questionnaires, data collection forms, and electronic data will be stored in locked files at the contractor's offices and will be accessible only to staff directly involved in the project. All members of the project will be 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 student and the setting, nearly any question about fighting, bullying, health behavior, family demographics, school satisfaction 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, 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 family socioeconomics, and supportiveness.

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 questions and questions on school health programs in the Administrator Survey were developed specifically to meet the program needs of NICHD, NHLBI, NIAAA, 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. Parental consent to participate in the survey will be obtained (Attachment 4).

A12. <u>Estimates of Hour Burden Including Annualized Hourly Costs</u>

The NEXT survey will address a sample of health-related factors according to rigorous research protocols. A nationally representative sample of U.S. students in grade 10 will be

surveyed and minority children will be over-sampled to permit comparisons across under-represented populations. The children will be students from approximately 80 schools; in order to assess health programs in those schools and how the school environment supports health behaviors, a school administrator from each school will be surveyed. The estimates provided in Tables A. 12-1 and A. 12-2 below are for the maximum number of students that may be surveyed assuming a 95% response rate (higher than any previous survey) in the maximum number of eligible students within the surveyed classrooms. In our pilot study with 9 14- and 15-year-olds, the average time to complete the survey was 35 min. including instructions. That will leave us approximately 10 min. to collect the anthropometric measures which are completed individually at a separate time. We are staffing the survey and anthropometric assessments with sufficient staff to efficiently move individual participants quickly through each stage.

Table A.12-1 Annual Burden for Affected Public: School-Age Children, Parents and School Administrators.

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses Per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Adolescents	2,700	1	0.75	2,025
Adolescents with additional assessments	750	1	2.5	1,875
Parents	750	1	0.17	128
School Administrators	80	1	0.33	26

The estimated annualized cost to respondents is $3,911 (Table 2). These costs were estimated for the 2009/2010 survey year only, not the entire duration of the project; annualized over the entire duration of the project, these costs would be reduced to $1,761. These estimates

were calculated using 2008 Department of Labor figures for wages of principals in high schools (grades 9 and 10) and of average wage and salaried employees, and assuming an annual increase of 3.75%, 50-week contract, and 40-hour week.

Table A.12-2 Annual Cost to Respondents – Survey Year Only.

Type of Respondents	Estimated Total Annual Burden Hours Requested	Estimated Annual Earnings During Survey	Average Hourly Earnings (with rounding)	Estimated Cost During Survey Year
Adolescents	11,004	$0.00	$0.00	$0.00
Adolescents with additional assessments	1,875	$0.00	$0.00	$0.00
Parents	128	$42,270	$21.93	$2,807
School Administrators	26	$84,913	$42.46	$1,104

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

No direct costs to the respondents themselves or to participating schools are anticipated.

A13. <u>Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers</u>

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

A14. <u>Annualized Cost to the Federal Government</u>

The survey is funded by a contract award to The CDM Group, Inc. at $6,274,313 for a 60-month period. Thus, the annualized contract cost is $1,568,578. These costs cover the following activities:

- Designing and planning the survey administration procedures
- Developing recruitment materials

- Developing web-based systems for collecting surveys from school administrators and health educators
- Pilot testing the questionnaires
- Developing protocols for anthropometric and biological data collection (see Attachments 9, 13, and 14)
- Developing a sampling plan
- Drawing a nationally representative sample
- Recruiting schools
- Recruiting and training field staff
- Collecting and processing data in school and during home visits
- 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 four NICHD/PRB, NHLBI, NIAAA, and HRSA/MCHB employees will be involved at the following rates and time allocation at 2,040 hours per year:

- Approximately 50% of time for the principal investigator at a salary of $75 per hour.
- Approximately 30% of time for each of two epidemiologist/analysts at salaries of $40 per hour.

Direct costs in NICHD/PRB, NHLBI, NIAAA, and HRSA/MCHB support staff time will be approximate $5,000 annually. Therefore, the annualized cost to the government will be $1,568,578 + $144,920 = $1,713,498.

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

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

Publication Plans**.** The U.S. data results will be 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 will include analyses of the results and assessment of the implications of results for federal, school, and community-based programs. Published articles will be 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, 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 between January 2010 through August 2013. Key project dates will occur during the following time periods:

Activity	Time Period
Collect data	January, 2010 through August, 2013
Process data	July, 2010 through December, 2013
Weight/clean data	July, 2010 through December, 2013
Produce U.S. data file	Decembers of 2010, 2011, 2012, and 2013
Analyze data	September, 2010 through August, 2014
Publish results	January, 2011 through January, 2015

Results will be published in early 2011 and periodically from 2011 through 2013, within the United States and internationally. As also noted in B.3 below, it is extremely important to initiate data collection before the end of the 2009/2010 school year. State education agencies and local school districts have told us that, during the spring semesters, schools are very busy with standardized testing, which the current administration has strongly encouraged. In addition, most school-based surveys occur in the spring months. Therefore, we have been strongly encouraged to conduct NEXT before spring to avoid competition with other large-scale data gathering and

testing activities. To achieve targeted school rates we request that OMB clear this by December 1, 2009 to begin school recruitment.

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.