Supporting Statement A

Supporting Statement A is completed when there are NO statistical methods employed. Otherwise, as separate files, complete both SSA and SSB.

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Supporting Statement A for

NEXT Generation Health Study – NICHD
[OMB No. 0925-0610
Expiration Date: April 30, 2016]]

Date: (Should be the date when the final version is sent to our office; which is after the 60-day comment

period)

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Check off which applies:
- New
- Revision
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- Emergency
- Existing

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A. Justification

Abstract

The NEXT Generation Health Study (NEXT) is a seven-year longitudinal assessment of a representative sample of U.S. adolescents and young adults starting at grade 10. The goals of NEXT include to: identify the trajectory of health status and health behaviors from mid-adolescence through the post high school years; examine individual predictors of the onset of key risk behaviors and risk indicators; to identify genetic, personal, family, school, and social/environmental factors that promote or sustain positive health behaviors; identify transition points in health risk and risk behaviors and changes in family, school, and social/environmental precursors to these transitions, and examine the role of potential gene-environment interactions in the development of health status and health behaviors. In addition, a representative subsample of overweight and normal weight adolescents has been identified and additional data on behavioral risk factors and biological markers and risk factors are gathered on these adolescents.

This study collects reliable and valid data on health behaviors and health indicators and their social, environmental, and biological contexts beginning with a nationally representative probability cohort of 10th-grade children in the U.S in 2010 and following them through 2016. NEXT data support NICHD, National Heart, Lung and Blood Institute (NHLBI), National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Maternal and Child Health Branch of the Health Resources and Services Administration (HRSA/MCHB) in fulfillment of program requirements that address supportive health environments for adolescents and young adults.

A.1   Circumstances Making the 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 reinstatement with change of the collection of information, which began in 2010 [OMB No. 0925-0610], in order to continue 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 (Waves 1 – 7) 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 obtain OMB clearance for the reinstatement of the previously approved collection of the Wave 7 assessment of health behavior and health status data in this cohort of U.S. adolescents.

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, 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, and substance use 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 seven years. We have tracked this cohort into early adulthood, permitting a unique opportunity to examine predictors of changes in health behaviors and mental health during significant family and career/education transitions. OMB clearance is needed to enable us to complete the seventh wave of data collection. 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 Health Behavior Branch (HBB) of NICHD. NICHD/HBB 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/HBB, and HRSA/MCHB. The foci of NICHD/HBB, 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. Data collection activities for the Wave 7 assessments will extend beyond the previous clearance expiration of April 30, 2016. Given that these data are collected annually, it is important to the quality of the study that that measures be completed in approximately the same time frame each year and that there not be an extended delay within an assessment period. This is a request for OMB clearance for three years from the approval date to continue the NEXT Generation Health Study.

A.2   Purpose and Use of the Information Collection

Survey Objectives and Information to be Collected

The NEXT Generation Health Study fills significant gaps in current research on adolescence as they transition into adulthood in the U.S. There are no current longitudinal surveys of obesogenic behaviors, substance use, 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, driving, and health status, including obesity, metabolic syndrome, and injuries due to motor vehicle crashes, 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, risky driving, and other health risk factors.

5. Examine the role of peer influences on diet, physical activity, sleep, substance use, 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 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 completed six annual surveys, had their height, weight and waist circumference measured. NEXT Plus participants have completed four annual in-depth assessments (Waves 1 – 4) including objective measures of physical activity, sedentary behavior, sleep, and anthropometrics (height, weight, and waist circumference); and twice (Waves 1 and 4) provided blood draws (finger stick) for 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. Separate subsamples have been assessed for carotid intima-media thickness (CIMT), and objective measures of driving. Peers of the NEXT Plus participants have completed surveys twice (Waves 4 and 6). Linkage of community level information on demographic characteristics (e.g. neighborhood socio-economic status, population density) and proximity of potential influences on health risk and health behavior (e.g., traffic patterns, walkability, food outlets, parks) have been obtained for their residence and school at Wave 1 and their residence at Wave 4. 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/HBB, NHLBI, NIAAA, and NIDA, and program goals held by HRSA/MCHB.

This application requests OMB clearance to complete the seventh annual survey, which was approved in the previous application (Expiration date April 30, 2016). The surveys will be conducted online or, when necessary, using hard copies. The content of the survey items has been kept very consistent to permit the analysis of changes in assessed behaviors. The NEXT survey is shown in Attachment 1 The Variable Source Table is available in Attachment 2.

The Wave 7 assessment also includes screening NEXT Plus participants for factors affecting cardiovascular health, in particular: objective measures of adolescent physical activity, sedentary behavior, and sleep; dietary intake; and biological and genetic markers for obesity and cardiovascular disease. Dietary intake data will be collected and analyzed using the Automated Self-Administered 24-hour Recall

(ASA24) system developed by the National Cancer Institute, Bethesda MD. Additionally, participants wear

an accelerometer and ActiWatch® for 7 days and concurrently complete a 3-day physical activity diary.

NEXT Plus participants undergo finger stick blood collection which will be analyzed for 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, and blood pressure will be measured.

Funding from the NICHD/HBB and HRSA/MCHB has been obligated beginning in FY2016 from

NICHD/HBB and HRSA/MCHB to cover the cost of conducting the study.

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/HBB for review and

approval. NICHD/HBB delivers the final data set to the collaborating agencies: NIAAA, NIDA, NCI, NIHMD,

and HRSA/MCHB. NICHD/HBB 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. The CDM group has

been funded to prepare a public use data sets (Waves 1 – 5) and associated materials in accordance with

the DASH website requirements (https://dash.nichd.nih.gov), to be delivered in the spring of 2017.

NICHD/HBB will subsequently submit the datasets and documentation to an NICHD approved website for

public access to the data.   NICHD/HBB will be responsible for preparing and submitting Waves 6 and 7 to

the same website to ensure access to the complete dataset.

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. In addition to the 24 publications listed in Attachment 3, there are approximately nine manuscripts under review at peer reviewed journals. Abstracts based on the NEXT datasets have been presented at many annual conferences, including the Society for Behavioral Medicine, Society for Prevention Research, International Society of Behavioral Nutrition and Physical Activity, American Academy of Health Behavior, Society for Research on Nicotine and Tobacco, and the American College of Sports Medicine.

Appropriateness and adequacy of sample, data collection, and analysis plans

Sampling Overview for the Main Study. The plans for sample size and data collection were approved as part of the previous applications. 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; 81 (59.1%) 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 2,874 (75.7%) students. 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. At Wave 6, 2,296 (80% of total sample) participants completed surveys. Among the NEXT Plus participants, 82% completed Wave 6 surveys, and 82% completed the most recent home visit (Wave 4). Participants were re-consented at the assessment

following their 18th birthday. This process is complete, and no consent forms will be used in the data

collection included in this application.

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.

Assessing 75% of the Wave 6 sample would result in a sample size of 1,722, providing more than an

adequate sample size. Previous wave-to-wave retention rates have met or exceeded 75%.

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. The Wave 6 sample of African Americans was 598, and of Hispanics was 693. Retention of at 80% of those samples will result in adequate samples for the planned subgroup analysis. Retention among African Americans and Hispanics from the base sample to Wave 6 was 87% and 83% respectively, further supporting that assessments at Wave 7 will yield adequate subsamples of these groups.

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 NEXT Plus In-Home 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. Consent was obtained from participants when they turned 18 for participating in the NEXT Plus assessments.

For specific hypotheses, the NEXT Plus subsample will be adequate to address primary hypotheses relating to obesity and cardiovascular disease. As noted above, retention in the NEXT Plus sample has been good (82% at Wave 6) suggesting sufficient participants will participate in the Wave 7 assessments. 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

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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. At Wave 6, 462 Next Plus students completed surveys, and is actually larger than the number participating at Wave 5, due to ongoing targeted retention strategies, suggesting the Wave 7 assessments are likely to be large enough to be sufficiently powered for the planned analysis. 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/HBB has collected 6 waves of data beginning in the spring of 2010. A general schedule of the data collection is provided below:

Table A2-1. NEXT and NEXT Plus assessments by Wave							
	Wave 1	Wave 2	Wave 3	Wave 4	Wave 5	Wave 6	**Wave 7[a]**
Assessment Year	2010	2011	2012	2013	2014	2015	**2016**
Grade	10	11	12	NA	NA	NA	**NA**
NEXT Full Sample (Spring)							
Survey (Spring)	X	X	X	X	X	X	**X**
Anthropometric Assessments[b]	X	X	X				**X**
Genetic Sample (saliva)	X						
NEXT Plus Assessments (Spring/Summer)							
Physical Activity/ Sleep[c]	X	X	X	X			**X**
Dietary Recall[d]	X	X	X	X			**X**
Blood (finger stick)	X			X			**X**
In-home assessment [e]	X			X			**X**
Carotid Intra- media Thickness					X		
Driving Risk				X	X	X	
Peer Survey				X		X	
[a]Assessments in this request ; Waves 1- 6 are complete							
[b]Height, weight, and waist circumference measured by professional field data collectors							
[c]Accelerometer, Actiwatch® , 3-day activity log							
[d]ASA24 - 24 hour dietary recall							
[e]Anthropometric assessment, blood pressure, report of chronic illness and medication use							

The protocols for the assessments of height, weight, waist circumference, blood pressure, collection of blood sample and a short survey completed during the home visit are found in Attachment 4 and Attachment 5, respectively.   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, their subcontractor. The same contractor has been awarded an IDIQ contract to complete tasks related to Waves 4 through 7. They have completed all phases of Waves 1 through 6. CDM will be awarded a task order for the data collection for Wave 7 in FY16.

Analytic approach

Both cross-sectional and longitudinal analyses have been employed and are ongoing. As indicated in the list of publications emerging from the study (Attachment 3), a range of analytic methods have been employed, including ANOVA, regression, growth modeling, and longitudinal transitional analyses.

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, driving, and health status, including obesity, metabolic syndrome, and injuries due to motor vehicle crashes, 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, risky driving, and other health risk factors.

5. Examine the role of peer influences on diet, physical activity, sleep, substance use, 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 examined in relation to consistency across waves and physical plausibility. 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. As noted elsewhere in this document, retention has been good across the six waves of the study. Moreover, missing data on individual variables within the waves of data collection has been manageable, usually with less than 5% of cases missing. Multiple imputation techniques have been employed to minimize the effects of missing data on statistical coefficients and standard errors.

Specifically, multiple imputation by chained equations (Little and Rubin, 2002, Buuren and Groothuis-Oudshoorn, 2011) have been used to impute missing outcome and independent variables resulted from both subject and item non-response values. This algorithm recursively imputed each missing variable by estimating its distribution conditional on other variables. Multiple imputed data sets are generated imputed (usually 50 data sets) were generated and analyzed; results are combined using Rubin's rule (Little and Rubin, 2002). 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. 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. Analysis of the first four waves of data have employed several longitudinal techniques, dependent on the research question, examining the trajectories from 10th grade through the transition out of high school (Lipsky et al, 2015, Simons-Morton, et al, 2015). These techniques have included transition models (Diggle et al, 2002; substance use, physical activity) and linear generalized estimating equations (nutrition). Autoregressive Latent Trajectory modeling (ALT) techniques, such as latent growth models, may

be used to identify patterns in growth curves and predictors of variations in these developmental patterns across the entire study period. 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 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 results 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?

<u>Mental well-being</u>

Research Question #1: Are adolescents who live in neighborhoods that are poor or have high levels of income inequality more likely to report depressive symptoms or thoughts of suicide?

Research Question #2: What proportion of adolescents with mental health problems have access to medical care?

Research Question #3: What is the prevalence of self-reported Attention Deficit Hyperactivity Disorder among adolescents, and what percent of those report treatment with ADHD medications?

Research Question #4: What is the relationship between mental health problems (self-reported depressive symptoms and suicidal behaviors, and self-reported diagnoses of depression and ADHD) and post-secondary education?

<u>Substance Use:</u>

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?

A.3   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 the annual surveys, and is available in a mobile format for those wishing to access it on their cell phone. 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 35 minutes.

The Information Technology System Security Plan provided in Attachment 6 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*. Specifically, a privacy impact assessment is in place, in accordance with OMB requirements (see Attachment 10).

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.

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

Despite persistent effort, we have identified no duplication of efforts to collect 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. While there are government funded studies of adolescent and young adult substance use, particularly college substance use, there do not appear to be any studies that examine the transition from high school to young adulthood that follow participants after high school who attend college full time, part time, do not attend high school, and those who work full time, part time, and do not work.

The NEXT Generation Health Study also surveyed school administrators to provide information about school and community context and the family environment.

**A.5	Impact on Small Businesses or Other Small Entities**

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

A.6   Consequences of Collecting the Information Less Frequently

The data collection schedule was previously approved by the OMB but clearance has expired prior

to completion of the study. This application is requesting clearance to complete the remaining wave of

assessments. 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), and 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.

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

This research study fully complies with 5 CFR 1320.5.

A.8.1   Comments in Response to the Federal Register Notice

The 60-day Federal Register Notice was published on March 10, 2016 (Volume 81, Number 47,

Pages 12744-12745). No public comments were received in response to the Notice.

A.8.2 Efforts to Consult Outside Agency

NEXT is reviewed annually by the HBB and the senior leadership of the Division of Intramural Population Health Research as part of the ongoing funding cycles. Additionally, the study is reviewed by NICHD Contracting Officers each year. Similarly, co-funders, including HRSA and NHLBI, review the study and its progress in order to justify continued funding agreements. The study procedures, measures, and progress are also reviewed by the NICHD IRB on a yearly basis. Study methods and analysis are reviewed by investigators in related fields with each journal submission and publication. Thus the study is under regular scrutiny from responsible agencies. The study design, methods, assessments, and analysis plans have not changed substantially since the last OMB approval. This application is to obtain clearance for the final assessments, the methods and procedures for which were previously approved.

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.

A.9   Explanation of Any Payment of 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 (David and Ware, 2014; Robinson, 2015). Using multiple retention strategies concurrently has been demonstrated to be useful in retaining adolescent samples in longitudinal research (Davis 2016). Financial incentives are used in the majority of studies utilizing multiple strategies (Robinson, 2015), and have been shown to be successful in behavioral health research (Schoeppe et. al, 2013), and for retaining samples tracking adolescents into young adulthood (Hanna, 2014). Thus, monetary incentives are one part of a comprehensive retention effort used in the NEXT study. The overall incentive structure for the annual survey was previously approved by the OMB, including the $55 gift card for Wave 7 participation. The amount of the Wave 7 incentive is similar to that used with a same-age sample for survey completion (Hanna, 2014), and represents an increase over the incentives participants received while in high school. Scaled incentive programs based on continued participation are implemented to increase retention (Hanna, 2014). The 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.

A.10   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. Study survey data and home visit data are directly entered into the secured data entry system.

Blood samples are directly to the lab for processing. Any data that may need to be collected manually (e.g.

loss/lack of internet connection in a home) are sent overnight to the home office for processing. 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 7). The protocol and survey has

been approved by the NICHD Institutional Review Board (IRB).

Procedures for obtaining consent were 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. 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.

All members of the project are required to sign a statement of personal commitment to guard the

confidentiality of data.

A.11   Justification for Sensitive Questions

Some of the questions on the NEXT questionnaire might be considered to cover sensitive topics. Depending on the participant and the setting, nearly any question about health behavior, suicidality, 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. In the six waves of data collection thus far, there have been no complaints or reports of concerns from participants nor their parents regarding the questions asked, types of data collected, or procedures used.

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.

A.12.1 Estimated Annualized Burden Hours

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 six Waves of data collection. We are requesting approval to complete the previously approved assessment in 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 eligible members of the cohort.

Table A.12-1 Annual Burden for Affected Public: Young Adults in the NEXT Cohort

Form name	Type of Respondents	Number of Respondents	Number of responses per respondent	Average Burden per response	Total Annual Burden Hour
NEXT Annual Survey	Young Adults	2,100	1	35/60	1,225
In-home Assessment[a]	Young Adults[b]	532	1	15/60	133
In-home Survey	Young Adults[b]	532	1	3/60	27
Total		2,100	3,164		1,385

[a]In Home Assessment includes height, weight, waist circumference, blood pressure, blood collection (finger stick)
[b]Next Plus participants, a subset of the 2100 who complete the NEXT annual survey

The estimated annualized cost to respondents for the 2016 (Wave 7) surveys is $20,692 (Table A.12-2). This estimate was calculated using 2015 Bureau of Labor Statistics figures for those aged 16 – 24 years (Bureau of Labor Statistics, 2015). Hourly earnings was estimated from the median weekly full time earnings for males and females (averaged; $503.53, Bureau of Labor Statistics, 2016) in the fourth quarter of 2015, divided by median hours worked (33.7).

Table A.12-2 Annual Cost to Respondents.

Type of Respondents	Number of Respondents	Average Burden per response	Hourly Wage Rate[a]	Respondent Cost
Young Adults	2,100	35/60	$14.94	$18,301.50

Type of Respondents	Number of Respondents	Average Burden per response	Hourly Wage Rate[a]	Respondent Cost
Young Adults[b]	532	15/60	$14.94	$1,987.02
Young Adults[c]	532	3/60	$14.94	$403.38
Total Respondent Cost	2,100	53/60		$20,691.90

[a]Bureau of Labor Statistics report from the fourth quarter of 2015. Median weekly earnings of males and females (averaged) ages 16 – 24 ($503.53 current dollars) divided by the median average weekly hours (33.7).
[b]Next Plus participants only, In-home Assessment
[c]Next Plus participants only, In-home Survey

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

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

A.14   Annualized Cost to the Federal Government

Annualized cost to the Federal Government is estimated as $1,635,250.00. Below are listed the estimated costs associated with the Wave 7 data collection. Estimated costs are based on previous budgets for the same work by the contractor, adjusted for increases in labor costs. The costs associated with this application were previously approved by the OMB and do not represent additional costs incurred by the study.

Staff	Grade/Step	Salary/Labor	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
HBB Contracting Officers Representatives	Title 42	$125,000.00	75%		$93,750.00
Contractor Cost					
Contractor off-site personnel (CDM)		$684,840.00		$284,208.00	$969,840.00
Travel associated with data collection					$185,000.00
Other costs associated with data collection					$386,660.00

Staff	Grade/Step	Salary/Labor	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Total					$1,635,250.00

A.15   Explanation for Program Changes or Adjustments

Changes made to the survey instrument reflect the aging of the study participants from mid-adolescents to emerging adults, and are listed in Attachment 8. Reinstatement is requested to allow us to complete a seventh wave of data collection, enabling us to examine questions regarding behavior change and development across emerging adulthood.

A.16   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

Results are made available promptly to the public through government publications, peer reviewed journal articles, and presentation at annual conferences of several relevant national and international organizations. As evidenced by the publications already produced from the study, the results of the analysis have implications for federal, school, and community-based programs. Published articles are sought in periodicals involved in health promotion, education, and other aspects of public health. Publications will include collaborations between NICHD/PRB, NHLBI, NIAAA, and HRSA/MCHB describing the program and policy implications. Analyses of behavioral research questions will also be pursued and will include collaborations with pre- and postdoctoral students through mechanisms available at NIH, such as the NIH Intramural Research Training program.

<u>Time Schedule for the Project</u>

The following is the previously approved schedule of activities for NEXT. 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 November 2016. We are currently on schedule to begin the Wave 7 data collection as soon as OMB reinstatement is received. Key project activities will occur during the following time periods:

A.16 -1 Project Time schedule

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

Results will continue to be published through 2018, within the United States and internationally. Previous annual assessments were collected in the Spring of each year from 2010 through 2015. 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.

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

All forms will display the OMB expiration date.

A.18   Exceptions to Certification for Paperwork Reduction Act Submissions: None

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

References are found in Attachment 9