Supporting Statement A for

Health Behaviors in School-Age Children - NICHD

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A1. Circumstances of Making the Collection of Information Necessary

Justification for the participation of the United States (U.S.) in the cross-national 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 an extension of collection of information to be completed during the 2009/2010 school year in order to continue to monitor trends in the U.S. student population. The U.S., represented by Principal Investigators from NICHD, was first accepted as a full participant in the international Health Behaviors in School-Age Children (HBSC) based on successful completion of a 1997/1998 U.S. nationally representative survey. **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), and the 2005/2006 survey was approved by OMB on January 17, 2006 (OMB #0925-0557, expires 01/31/09).** The purpose of this OMB application is to provide an extension of the U.S. survey, allowing the fourth administration of the U.S. HBSC and permitting the U.S. to continue as a full study participant for this seventh round of the international HBSC survey.

Background. Accurate estimation of the prevalence of children's health and health 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., 2008). There are a number of federally-funded studies of health behaviors that either focus on adults (e.g., the Behavioral Risk Factor Surveillance System (BRFSS) and the National Health Interview Survey (NHIS)) or are no longer being conducted with adolescents (e.g., the National Longitudinal Study of Adolescent Health [Add Health]). Currently in the U.S., the four major assessments of youth health and health risk behaviors either focus on high school students (Youth Risk Behavior Surveillance [YRBS]; Eaton et al., 2006) or on substance use of adolescents (National Survey on Drug Use and Health [NSDUH], OMB No. 0930-0110, exp. date 01/31/2009; Monitoring the Future [MTF]; Johnston et al., 2007; National Youth Tobacco Survey [NYTS], OMB No. 0920-0621, exp date 12/31/2008). Neither YRBS nor MTF includes children as young as those in HBSC. The NSDUH includes children as young as 12, but the methodology is substantially different from that used in HBSC. The NSDUH is conducted with one-on-one interviews in the home and requires parental permission to interview the children; as the Substance Use and Mental Health Services Administration (SAMHSA) acknowledges, this results in a substantially lower (and perhaps non-representative) rate of reported substance use compared to confidential surveys administered in a school setting without parents present. The NYTS includes children in grades 6 through 12 and utilizes an anonymous self-administered questionnaire. However, question content focuses solely on the use of tobacco products. The HBSC survey includes a range of health behaviors, not just substance or tobacco use. HBSC includes a nationally representative sample of children younger than any other national sample. Only HBSC uses a standardized set of questions permitting international comparisons. The HBSC Study, 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 every four years. The U.S. previously conducted HBSC surveys in 1997/1998, 2001/2002, and 2005/2006. The U.S. survey parallels the international survey of 11-, 13-, and 15-year-old youth but also expands the sample to provide a representative national sample of 6th through 10th graders. Because core survey items have remained consistent both nationally and internationally since 2001, the 2009/2010 survey would provide essential data for examining national and international trends. Thus, the extension of the study would provide a sample suitable for national comparisons between age/grade groups, national trend analyses, cross-national comparisons, and international trend analyses (Currie et al., 2004). The U.S. component of the HBSC study will also incorporate an Administrator Survey and other data files to obtain related information on school-level health programs and community-level contextual data to support NICHD 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 (Attachment 1, Data Collection Instruments).

Need. Incorporation of school health program and community context data with research on adolescent health behavior provides a unique source of data for evidence-based research supporting the missions of both the Prevention Research Branch (PRB) of NICHD 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. HRSA/MCHB has the primary responsibility for promoting and improving the health of adolescents through program and policy. The 2009/2010 HBSC results will have significant implications for program and policy development, health education,

public information campaigns, demonstration programs, professional education/training, and research activities. The HBSC goal is to use the information to improve long-term health consequences resulting from adolescent behavior and the quality of health promotion 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. NICHD/PRB has focused on 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 consideration is necessary for participation with the HBSC by incorporation of U.S. data and for access to data from other countries. Full participation requires that mandatory questions for a representative population be fielded in the same school year as the HBSC survey. Successful completion of the 1997/1998, 2001/2002, and the 2005/2006 U.S. surveys allowed U.S. access to fully comparable data from participating countries. Furthermore, all core survey items will be identical over three administrations (2001/2002, 2005/2006, and 2009/2010); thus the basic requirements for national and international trend analyses will be met for all areas of health assessed. The U.S. survey must be completed by February 2010 to meet the age and timing requirements of the HBSC. Fielding the

survey no later than October 2009 would be preferable to meet age requirements for the youngest age group and minimize school burden from other surveys or student testing schedules.

The HBSC questionnaire contains a section that is **mandatory** for all cycles, and a focus section that is **mandatory** for the current cycle only. A third section of **optional packages** includes questions that must be asked in a consistent format if they are to be included in the international data file. The packages include the minimum questions required to address a research question. All survey questions (optional and mandatory) have undergone rigorous testing prior to inclusion in the HBSC package. New questions are only considered after they have been tested in more than one country and have evidence of validity and reliability. The 2009/2010 U.S. student survey must use the exact form of the HBSC mandatory and focus questions to participate in order to obtain comparability across countries and to use data from the cross-national comparisons. Mandatory and focus questions may be reworded or adapted only to account for national context and to clarify the questions. Otherwise, the wording and categories must remain the same. The questions in the U.S. 2009/2010 survey have all been used in previous research studies, even if not included among the international HBSC authorized questions. The questions have been included in surveys previously approved by OMB. The HBSC U.S. Surveys and a Variable-Source table, which identifies mandatory and optional items, as well as which items have previous OMB approval, are found in Attachment 3.

This is a request for OMB clearance of the Health Behaviors in School-Age Children Survey, 2009/2010.

A2. <u>Purpose and Use of Information</u>

Survey Objectives and Information to be Collected. The primary goal for the 2009/2010 U.S. study is to determine the influence of school, family, peers, and the supportive environment on behaviors associated with both positive and negative health outcomes. The administrator survey will support NICHD/PRB, HRSA/MCHB, and other agencies and organizations in addressing school health programs and policies that affect health outcomes. The most important aspect of this study is that the adolescents are viewed in their social context, not limited to individual indicator measures of negative or positive health and behavioral outcomes. Most of the major risk behaviors targeted in Healthy People 2010 are monitored for high school youth through the Youth Risk Behavior Surveillance System (YRBS) of the CDC (OMB No.: 0920-0493, Expiration Date 11/30/2007) and Monitoring the Future (MTF) (Drug Use and Lifestyles of American Youth, Grant Number: 3 R01 DA 01411). However, students at younger ages are not included in these surveys. The HBSC places the health indicators in their social and physical context, providing a depth of information supportive of multi-variable research. It also includes the pre-teen and transition ages when health behaviors are developing, providing an opportunity to assess precursor behavior for the high school years where health risk behaviors and outcomes may be more entrenched and intervention less effective.

The HBSC emphasizes different aspects of adolescent health and behaviors in each survey round. Factors associated with family structure, interactions, and support, obesity, nutrition, physical exercise, use of time (after school, computers, parent and peer interactions), social inequality, diversity, as well as injury and violence will be emphasized in mandatory questions to be collected in all countries in 2009/2010 and optional questions used by some countries.

The school-based survey of students provides limited information on school health programs and the supportive social and community environment. Linkage of school and community level information will be included in the full U.S. survey 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. To support HRSA/MCHB program and research data requirements, an Administrator Survey will be completed 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 HBSC school administrator survey which has been administered in previous cycles of HBSC, enabling comparisons across countries. Extreme care will be taken to exclude the possibility of identification of schools or communities due to the Administrator Survey. The Administrator Survey for school principals or their designated alternates is shown in Attachment 2.

All of these factors are associated with the leading health indicators of the U.S. Healthy People 2010, making the HBSC focus 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 and the same program goals held by HRSA/MCHB. Budget has been obligated beginning in FY2008 from the NICHD/PRB and, through an Intra-Agency Agreement, from HRSA/MCHB to cover the cost of performing the U.S. study to assist in meeting their program needs.

Receipt and Distribution of Data. The data will be collected, merged, and cleaned by The CDM Group and Abt Associates. These organizations will be responsible for the data provided to the HBSC Data Coordinating Center and will deliver a final data set on each survey 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 agency, 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 mandatory and optional questions in the questionnaires 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, and diversity. The latter factors are also addressed by the linked 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. The 1997/1998 U.S. component of the HBSC data was provided to the workshop participants to allow multi-level analysis of contextual data that can be used for findings on positive well-being influences. The public use files for 1997/1998 and 2001/2002 are available and the 2005/2006 public access data files are in preparation.

Past Uses of the Survey Data. Past uses of the U.S. survey data already demonstrate applications to research, program, and policy. NICHD emphasized injury and violence in the first publication derived from the 1997/1998 results. A number of significant papers have been published or accepted/submitted for publication or presented to various audiences. Findings on school safety, fighting and bullying were included in the Department of Education 1999 Annual Report to Congress on School Safety. Findings from the Journal of the American Medical Association publication on the psychosocial aspects of bullying behavior influenced HRSA/MCHB to support media efforts targeted to modifying bullying. Published findings on injury data in the U.S. and other countries shows strong association of destructive behaviors, alcohol use and smoking behaviors with fighting and injury. However, fighting was found to be a normative behavior with little predictive value for other problem behaviors and not associated with high rates of homicide in the U.S. compared to other countries. Related findings were presented in an archived video cast on International Perspectives of Youth Violence, sponsored by HRSA/MCHB on June 26, 2001. More recent publications have identified racial/ethnic differences in the determinants of bullying and victimization, an index that identifies adolescents at risk for violent behavior, the psychological and social benefits of physical activity and liabilities of sedentary behavior, and the effects of state and national policies on adolescent use

of tobacco, alcohol and marijuana.

Findings published in the HBSC International Report on preliminary international comparisons from bivariate review demonstrated a number of priority research areas of concern for the U.S. These included topics related to family structure, obesity, nutrition, psychosomatic symptoms with associated medication use, feeling of support from other students, etc. At the same time, our relatively low prevalence of smoking at age 15 compared to other countries reinforces the U.S. policy efforts to reduce smoking behavior in adolescents. Highlights of the comparative findings have been published in the American Journal of School Health. Many of the international comparisons reinforce concerns identified in the Healthy People 2010 leading health indicators, while some findings suggest health concerns that should be investigated in the U.S. These topics will be included again in the U.S. HBSC – with many required as mandatory for all countries based on findings in previous surveys. An international report of the 2005/2006 survey showing comparisons on various topics across the 40 participating countries are available via the WHO website: http://www.euro.who.int/InformationSources/Publications/Catalogue/20080616_1.

The number of countries participating in HBSC has grown every cycle; however, the 40 countries currently participating in HBSC are: Albania, Armenia, Austria, Belgium, Bulgaria, Canada, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Greenland, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, TFYR Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, and USA.

Evaluation Components**.** The evaluation will be completed in four phases, using both the full U.S. files and working in collaboration with other countries:

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

Production of the international report in collaboration with Principal Investigators (PI's) of other countries.

U.S. research studies on behavioral determinants through collaboration of NICHD and HRSA/MCHB scientific and post-doctoral personnel.

Collaboration with individual countries, such as Canada, on specific foci of common concern.

Appropriateness and adequacy of sample, data collection, and analysis plans. HBSC requires that each country submit a representative national school-based sample for students at the average ages of 11.5, 13.5, and 15.5 years and who are present at school during the survey time period. These ages are required in order to provide comparability at similar developmental stages across countries. Average design effect should be 1.4 for most variables, resulting in an expected sample size of 1,670 students at each year of age. Each country must submit their data to the HBSC data coordinating center by July 1, 2010, for data cleaning and verification. Countries are accepted for participation only if their data are complete, questions were asked in exactly comparable formats, and students meet the average age requirements. Preliminary cleaned data files are returned to each country for verification with final international files to be released to each qualifying country during 2011. Data for each country are available for use by other countries only with permission of the PI's of the countries whose data will be used.

The U.S. expects to meet the basic sample requirements of the HBSC and also provide a full U.S. study that will over-sample African-American and Hispanic adolescents, in about the same manner as the 1997/1998, 2001/2002, and 2005/2006 surveys. Public, private, and parochial schools will be included. Overall sample precision should provide national estimates at the 95% confidence level and minority estimates at the 90% level. See respondent universe and statistical sampling plan for the U.S. in Section B.

Appropriateness of data collection plans. HBSC requires completion of the survey for 2009/2010 school year, for a country to become a full participant with comparable data. NICHD/PRB expects the survey to be completed during the fall of 2009 (October 2009) and the winter of 2010 (February 2010, depending on individual school schedules and availability. In order to assure that we can examine trends over time, all HBSC mandatory questions will remain the same in the 2009/2010 survey as those in 2001/2002 and 2005/2006. The contract to field the survey was awarded on June 1, 2008, 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, questionnaire formatting, administration of the surveys, and completion of the final datasets by the required deadlines.

Analysis plans. International analysis and dissemination plans were coordinated by the HBSC Policy Development Group. Products will include one or more international publications showing the comparisons among countries and some analyses of mandatory question variable for all countries. Many of these products will be disseminated through the series, “Health Policy for Children and Adolescents (HEPCA) published by the WHO Regional Office for Europe and coordinated by the HBSC publications center at Bielefeld University in Germany. The

International Journal of Public Health has agreed to publish an issue of HBSC papers from the 2005/2006 survey. Similar arrangements may be forthcoming for the 2009/2010 survey. Other outlets for HBSC publications have many of the major research journals including the Journal of the American Medical Association, Pediatrics, and Journal of Adolescent Health.

Descriptive analyses of the data by school and in aggregate will be conducted to characterize student participation, item non-response, scale internal consistency, and distributions. Multiple regression analysis methods available for complex, weighted survey data, available in SUDAAN and SAS, will be employed. Analyses will be conducted using the data from the nearly 14,000 6th to10th grade U.S. students. Other analyses will be conducted with data comparing the U.S. with selected other HBSC countries or making cross-national comparisons with all participating HBSC countries. Examples of the kinds of research questions that will be addressed:

Variables: The dependent outcome parameters and independent variables include the following:

Outcome Parameters.

Violence: bullying, fighting, and weapon carrying;

Risk Behavior: alcohol use, smoking, marijuana, drug use (15-year-old only);

Preventive Health Behaviors: physical activity, eating habits, dental hygiene;

Subjective and physical health: height, weight, body image, asthma, acne, depression and psychosomatic complaints.

Independent Variables.

School and environment: school satisfaction, academic performance, teacher expectation of

student performance, and supportive students;

Social inequality and family environment: father's occupation, mother's occupation, supportive parents, home-crowding, family holidays, and computer ownership;

Demographics: age, sex, family structure, race, ethnicity, and school-grade.

Analytic approach. The international sample is expected to produce U.S. national estimates at a 95% confidence level at ages 11.5, 13.5, and 15.5 years. The U.S. sample will provide equivalent power for grades 6 through 10. Estimates for the minority-oversample should be reliable at a 90% confidence level. All analyses will include weighting and variance estimates that account for the multistage complex sample design. Based on previous response rates to prior surveys, 80 % of schools and 85% of students are expected to respond. Response rate for administrator surveys was 97%.

Multilevel modeling methods appropriate to complex survey data will be used for analyses to be published in peer reviewed journals. Analysis will be completed in three phases as data become available: (1) U.S. prevalence, trends over time, and cross-sectional associations by age, sex, race, etc.; (2) bi-national comparisons of prevalence, trends, and associations by age, sex, SES, etc.; and (2) multi-national comparisons of prevalence, trends and associations by age, sex, etc. Examples of research questions that would guide analyses for a variety of outcomes follow.

Obesity, diet and physical activity. What is the prevalence of physical activity, sedentary behaviors, diet, obesity, and dieting among U.S. adolescents? To what extent has diet, obesity, physical activity, and sedentary behavior changed over time? What psycho-social and environmental factors are associated with diet, physical activity, and sedentary behavior? How

do these outcomes vary in the U.S. and Canada and other countries?

Violence and Bullying. What is the prevalence of violent and bullying behavior in the U.S.? To what extent does it vary by age, sex, race, SES, psychosocial, and environmental factors? To what extent have these behaviors varied over time and to what extent do they vary between the U.S., Canada, and other countries?

Substance Use. What is the prevalence of smoking, drinking, and marijuana use by age/grade, sex, race, geographic region, SES, and family composition? Has prevalence changed over time? What factors are associated with the use of these substances? Do prevalence and associations vary by country?

A3. Use of Information Technology and Burden Reduction

As required in 5 CRF 1320.5 (d2), the investigators researched technological advances in data collection that might reduce participants' response burden. A school-based survey, as required by the HBSC, is more efficient than implementing a web-based survey or computer-assisted telephone interviews from household surveys to identify the needed student samples. The 2009/2010HBSC 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 2009/2010HBSC 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.

The administrator surveys will be completed via hard copy survey booklets provided prior to the data collection visit and scanned for data entry directly into file. During the 2005/2006 HBSC Study, administrators were given the choice of completing the survey on line or by hard copy. The majority of administrators chose to complete the survey by means of hard copy format.

While the main student data collection is most efficient when implemented in the classrooms, web-based survey techniques will be used in one area. Students who are absent from school on the day of the survey administration will be asked to complete the survey on-line (in private; in school; during the school day), improving the staffing efficiency.

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. These efforts identified several related national school-based surveys. None of the U.S. surveys include the mandatory questions in the format required by the HBSC. The 2001/2002 NICHD survey (OMB #0915-0254, expired 10/31/04) piloted most of the HBSC questions, including some similar questions from the YRBS (OMB No.: 0920-0493, Expiration Date 11/30/07). The YRBS is conducted in grades 9-12. Since 1975, MTF, a widely-cited survey funded by a grant from the National Institute on Drug Abuse, has gathered data annually on drug use and related attitudes. The National Survey on Drug Use and Health (NSDUH) (OMB No. 0930-0110, exp. date 01/31/2009) uses in-home interviews and includes children as young as 12, but the methodology is substantially different from that used in HBSC. The National Youth Tobacco Survey (OMB

No. 0920-0621, exp. date 12/31/2008) includes children in grades 6 through 12 and utilizes an anonymous self-administered questionnaire. However, question content focuses solely on the use of tobacco products. Overall, the YRBS, NSDUH, MTF, and NYTS do not include the HBSC required questions that allow assessment of interrelationships among health behaviors, family, school, and peer influences. Nor do they address the youngest age group required by the HBSC. A large number of individuals in Federal agencies with similar missions were consulted to account for duplication or overlap in preparation for the 2009/2010HBSC as noted in Section 8.

Ultimately, none of the Federal studies listed above will allow direct comparability of U.S. data to information collected in other nations or permit continued trend analyses of indicators assessed in the 1997/1998, 2001/2002, and 2005/06 U.S. HBSC surveys. None have allowed estimation of the key outcome variables of the 2009/2010HBSC Study. None extended the selected YRBS data elements, previously limited to students in grades 9-12, to younger students or focused on family, school, and peer influences. Although it might be possible to re-analyze YRBS or NSDUH data to draw tentative conclusions on a handful of topics about the comparability of some of the health behaviors among U.S. youth in 8th and 10th grade and their counterparts in the 40 other HBSC nations, most of the questions in the 2009/2010HBSC mandatory questionnaire differ from the NSDUH and YRBS questions. Moreover, the 2009/2010HBSC was designed by consensus of the participating nations to address issues that could appropriately be asked in schools in all countries.

A5. <u>Impact on Small Business or Other Small Entities</u>

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

A6. <u>Consequences of Collecting the Information Less Frequently</u>

The WHO cross-national study is conducted at the same time every four years. Failure to maintain this schedule will affect the ability to analyze trends with the U.S. and eliminate any possibility of making cross-country comparisons.

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 Federal Register Notice was published on September 12, 2008 (Volume 73, Number 128, pages 53030-53031). One public comment was received, asking for a copy of the data collection plans for the proposed collection. A copy of the protocol and the proposed instrument were sent in response to the inquiry.

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 2008. Research members of 40 HBSC countries reviewed and recommended all mandatory and optional questions for the 2009/2010 study according to their specialty interests, as members of HBSC focus groups. The HBSC member countries have been listed above. The HBSC Scientific Development Group required that all of the mandatory and optional questions be piloted and reviewed externally before the questions could be included in the HBSC protocol. Besides the review of focus group questions, global external review was required under the HBSC protocol for significance of research topics, concepts, clarity of language used, and validity of measures to address those topics. Many of these reviews were completed by e-mail. In addition, the U.S. PI's obtained external statistical review of three proposed sample designs to

meet HBSC and U.S. criteria for valid nationally representative estimates based on requirements for age, adequate sampling response, efficiency, and other issues. Consultations from other agencies and national organizations were also obtained concerning the usefulness and validity of the linked QED and CCD data files and Administrator Survey questions to address program issues and the social community context. The protocol and surveys were also reviewed by the NICHD Director of Intramural Research and a panel of independent extramural investigators selected by the Director.

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

A9. Explanation of Any Payment or Gift to Respondents

The 1997/1998 HBSC offered no financial incentives to individual respondents. However, because OMB encouraged the government to consider payments to schools to increase the school participation rate on the national YRBS, schools in the 2001/2002 HBSC received stipends to cover some of the costs of involvement in survey administration. Given the increase in competing demands on schools, the fact that other OMB-approved and non-OMB approved surveys offer financial incentives to schools, and that OMB suggested even higher incentives might be appropriate in the 2005/2006 review, NICHD/PRB and HRSA/MCHB has determined that the continued use of incentives is necessary to encourage school participation and improve response rates. Thus, NICHD/PRB is offering monetary incentives to participating schools in the amount of $500 per school for the 2009/2010 survey. Classrooms will also receive $25 each in

on-line gift certificates to thank them for participating. This will be discussed further in B3.

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

The Privacy Act does not apply to the data collection since no personal identifiers are collected. Regulations for Protection of Human Subjects (45 CFR) do apply. The protocol and surveys are currently under review by the NICHD Institutional Review Board (IRB). Final determinations will be provided to OMB as soon as they are completed and before the final OMB determination.

Procedures for obtaining consent are consistent with those of other U.S. national studies, such as the YRBS, in which anonymous data are collected from students at school (Brener et al., 2004; Eaton et al., 2004). It is anticipated that approximately 65% of the schools will permit passive consent and 35% of schools that will require active parental permission. In the passive consent situations, parents will be provided with information about the study, will be able to review the survey instrument, and can refuse to allow their child to participate. In the active consent cases, parents will be provided 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. 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, 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 anonymity will be maintained throughout data collection, that all data will be safeguarded closely, and that no institutional or individual identifiers will be used in study reports. Anonymity will be promised to students and their parents on parental permission and student assent forms.

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, but the booklets will be distributed randomly to the students; codes will not be linked anywhere to a student's identity. 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.

During data processing, all completed questionnaires 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. <u>Justification for Sensitive Questions</u>

Some of the questions on the 2009/2010HBSC 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. A 10th-grade version of the survey has been created so that more sensitive questions on drug use will only be administered to older students. The behaviors covered in the survey are among the major behaviors known to increase mortality and morbidity, and multiple NICHD/PRB 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 2009/2010HBSC questions were developed in close cooperation with representatives from school systems around the world, 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, HRSA, and other Federal agencies and have been administered in previous rounds of HBSC surveys. 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.

Since the 2009/2010HBSC 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. Estimates of Hour Burden Including Annualized Hourly Costs

The 2009/2010 U.S. survey will address a sample of health-related factors according to rigorous research protocols developed by the HBSC. The international HBSC survey requires at least 1,536 youth in each age group and a total of 5,000 students. In the U.S., a nationally representative sample of children in grades 6 through 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 386 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.

Table A.12-1 Affected Public: School-Age Children 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	14,672	1	0.75	11, 004
School Administrators	386	1	0.33	127

The estimated annualized cost to respondents is $5,392 (Table A.12-2). 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 $1,348. These estimates were calculated using 2008 Department of Labor figures for wages of principals in high schools (grades 9 and 10), middle schools (grades 7 and 8) and elementary schools (grade 6) and assuming an annual increase of 3.75%, 50-week contract, and 40-hour week.

Table A.12-2 Annualized 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
School Administrators	127	$84,913	$42.46	$5,392

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

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

A14. Annualized Cost to the Federal Government

The survey is funded by a contract award to The CDM Group, Inc. at $1,995,319 for a 40-month period. Thus, the annualized contract cost is $498,830. 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 a sampling plan
- Drawing a nationally representative sample
- Recruiting schools
- Recruiting and training field staff
- Collecting and processing data
- Weighting and cleaning of data
- Providing and verifying data to international file coordinators
- 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 and HRSA/MCHB employees will be involved at the following rates and time allocation at 2,040 hours per year:

- Approximately 60% of time for the principal investigator at a salary of $72 per hour.
- Approximately 30% of time for each of two epidemiologist/analysts at salaries of $40 per hour.

Direct costs in NICHD/PRB and HRSA/MCHB support staff time will approximate $5,000 annually. Therefore, the annualized cost to the government will be $498,830 + $144,920 = $642,750.

A15. Explanation for Program Changes or Adjustments

This is an extension of a collection of information. Changes in burden reflect adjustments due to changes in the size of the target population (U.S. school-aged children in grades 6 through 10 and U.S. school children ages 11, 13, and 15) as well as slight modifications of the HBSC international requirements.

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 HBSC. The HBSC requires that those files be submitted to the HBSC Data Coordinating Center by July 2010. The U.S. data files will subsequently be released as a public use data set.

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 2005/06 HBSC Study." Publications will include collaborations between NICHD/PRB and HRSA/MCHB describing the program and policy implications.

(2) Publication of the International Report by the HBSC (see http://www.euro.who.int/InformationSources/Publications/Catalogue/20080616_1).

(3) The HBSC Data Coordinating Center will provide public access to the international data file, including U.S. data, via an Internet Web site at the HBSC Data Coordinating Center three years after release of the international data to the participating countries.

(4) 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 the 2009/2010HBSC, in terms of months after receipt of OMB clearance. The end date for data collection is constrained by HBSC requirements. Data collection will occur between October 2009 and February, 2010. Key project dates will occur during the following time periods:

Activity	Time Period
Collect data	October, 2009 through February, 2010
Process data	February, 2010 through April, 2010
Weight/clean data	April, 2010 through May, 2010
Produce International data file	June, 2010
Produce U.S. data file	August, 2010

Analyze data	September, 2010 through August, 2012
Publish results	January, 2011 through January, 2013

Results will be published in early 2011 and periodically from 2011 through 2013, within the United States and internationally. U.S. results will be prepared prior to international studies. The HBSC Data Coordinating Center anticipates that the merged international file will be available for preliminary review in fall of 2010 with the final file available for use in 2011.

As also noted in B.3 below, it is extremely important to complete 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 the HBSC before spring to avoid competition with other large-scale data gathering and testing activities. To achieve targeted school rates and comply with the HBSC protocol, we request that OMB clear this extension of data collection by March 1, 2009 to begin school recruitment. We do not have the option of delaying the survey until the next fall because this would render the United States out of compliance with HBSC protocols and exclude the Unites States from the current and future cycles of the HBSC.

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.