01/27/10

Supporting Statement

for

Longitudinal Follow-up of Youth with Attention-Deficit/Hyperactivity Disorder Identified in Community Settings: Examining Health Status, Correlates, and Effects Associated with Treatment for ADHD

Revision of 0920-0747

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A. 1. Circumstances Making the Collection of Information Necessary

Background

This data collection activity is a Revision of an active ICR (OMB 0920-0747) and is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241; Attachment A1). It is being revised to extend the data collection activities for two additional waves of assessments. The proposed study is also consistent with the aims of the Children's Health Act of 2000 (Attachment A2) which mandates the National Center on Birth Defects and Developmental Disabilities (NCBDDD) to promote research on the causes, diagnosis, early detection, prevention, control, and treatment of Autism and related developmental disorders. Attention-Deficit/Hyperactivity Disorder (ADHD) is a related neuro-developmental disorder of considerable interest to NCBDDD. The proposed research in ADHD is also consistent with the CDC mission to promote health and quality of life by preventing and controlling disease, injury, and disability by a variety of means, including conducting research to enhance prevention.

ADHD is the one of the most common neurobehavioral disorders of childhood, and is characterized by inattention, impulsivity/hyperactivity or both, such that daily functioning is compromised in multiple settings (DSM-IV-TR, 2000 diagnostic criteria; APA, 2000). ADHD affects about 3-7% of school age children with recent estimates suggesting higher rates in some socio-demographic groups. CDC estimates that roughly 2.5 million children were taking medications to treat ADHD in 2003, although substantial disparities exist in rates of both parent-reported diagnosis and treatment across US states (MMWR, 2005). ADHD often persists into adolescence and can affect behavior and functioning even in adults. However, little is known about the disorder's developmental trajectory from non-clinical samples of youth identified and treated for ADHD through usual community care.

ADHD poses substantial costs both to families and society. The disorder has been associated with strained familial and peer relationships, suboptimal educational achievement, delinquent and antisocial behavior, early substance use and/or abuse, and increased risk for unintentional injuries, as well as a litany of psychiatric comorbidities (Rowland et al., 2002; AACAP, 1997; AAP, 2001). Health-care costs associated with ADHD are conservatively estimated at $3.3 billion annually (Birnbaum, 2005). Effective pharmacological and psychosocial treatments exist, but their long-term effects have not been adequately studied. For example, persistent and negative side effects of stimulants have been documented, including sleep disturbances, reduced appetite, and suppressed growth, but there is limited longitudinal data.

Given the prevalence of ADHD and the millions of children who are currently taking medication for this disorder, the health risks and benefits associated with treatment modality and compliance in usual community care merit further investigation. Information on health risk behaviors associated with ADHD is equally important for the purposes of treatment planning and the development of public health prevention strategies to reduce health risks in this population. Very little is known about the age of emergence, rates, types, and behaviors associated with health risks among youth with ADHD in non-clinical populations. Longitudinal monitoring and community-based research activities that focus on the correlates of ADHD and its diagnosis and treatment are needed.

Very few longitudinal samples of children with ADHD exist and the most notable include persons with ADHD identified in clinical settings over 20 years ago when diagnostic criteria (even the name of the disorder) were different. Further, medication treatment for ADHD has become increasingly common in both adult and child populations, with several new formulations (e.g., non-stimulants now used frequently in pediatric practice). The multi-modal treatment study of ADHD (MTA) continues to

follow their cohort of youth with ADHD who enrolled in a rigorous, intensive study of ADHD treatment modalities; however, these youth had to meet strict inclusion criteria and likely do not represent average children with ADHD receiving usual community care for ADHD (MTA Cooperative Group, 1999). Hinshaw (2006) recently conducted a 5 year prospective study of 11-18 year old girls with and without ADHD. This study contributed important information about the history of ADHD in girls, an area that has been understudied. However, it was limited to girls only and was not a community-based sample. There remains considerable interest in the long-term effects of treatments, lack of treatment, and quality of care in average US communities that emphasizes the public health importance of longitudinal research in this area.

The initial Project to Learn about ADHD in Youth (PLAY) study (OMB application No. 0920-0584) involved school district-wide screening at two sites (Oklahoma and South Carolina). A community-based sample of children with probable ADHD based on the screening data and a random sample of remaining children participated in an in-depth interview to provide information on diagnosis, symptoms, and associated health risk. The participants who completed the baseline interview were now invited to participate in a longitudinal follow up study, the PLAY study follow-up (OMB application No. 0920-0747). Specifically, the Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities, has provided funding to the University of Oklahoma Health Sciences Center and University of South Carolina to study the long-term outcomes and health status of children with ADHD identified and treated in community settings through a systematic follow-up of the subjects who participated in the PLAY study for 3 waves of annual data collection.

The proposed revision aims to follow up the participants for two additional annual assessments, i.e., wave 4 and 5, following the participants, who were initially recruited in elementary school, into older adolescence towards young adulthood. Funding will be provided to the University of South Carolina, where sufficient numbers of participants were able to be retained in the first waves of follow-up data collection. The additional waves for PLAY study follow-up will allow the CDC to address the imminent public health concerns around ADHD diagnosis and treatment and better understand and promote the health status of youth with ADHD particularly in older adolescents.

Privacy Impact Assessment

The PLAY study follow-up (OMB application No. 0920-0747) was reviewed and deemed subject to the Privacy Act. The Privacy Act System of Records Notice Number is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

Overview of the Data Collection System

The data collection system for waves 4-5 will follow the system used in the PLAY study follow-up for waves 1-3 and will consist of annual interviews of the participants and their proxy respondents (such as a parent or caregiver). Quarterly contact with the participants is planned to gather information about ADHD treatment and school events that participants otherwise would not be able to remember in detail, and to collect current contact information for retention purposes. Semi-annual assessment of symptoms will also be conducted to document changes over time and to maximize accuracy of participants' recall.

The data collection methods will include a combination of personal interview and paper-based self report for the annual and semi-annual data collection, as well as telephone interviews for quarterly updates. Data will be collected by trained research assistants at the University of South Carolina and maintained there until the close of the study. When there is no further need to identify a child or his or her address, the master identification file that links participant number with individual name will be destroyed. De-identified data sets will be maintained at the CDC.

Items of Information to be Collected

Data will be collected on diagnoses, symptoms, outcomes, risk factors and health promotion behavior. Potentially identifying information in the permanent dataset will include date of birth, driver's license, education records, and employment status of the youth. Additionally, names, mailing addresses, phone numbers, email addresses will be maintained by the University of South Carolina. These data will be de-identified prior to its transmission to CDC. See Section A.10 for further description of the process for de-identifying data.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This information collection does not involve web-based data collection methods.

A. 2. Purpose and Use of Information Collection

The proposed research will provide longitudinal information on community-based rates and correlates of ADHD, comorbidity, patterns of service, association with risk behaviors, role of developmental assets in outcomes, impact on quality of life, and feasibility of large scale screening and long-term follow-up assessment. It will also provide data on risk factors in elementary age that predict poor outcomes in adolescence, particularly later adolescence assessed in Wave 4 and 5. Long-term outcome and health status information will be utilized by CDC, other federal agencies, researchers, and practitioners, in developing and evaluating better interventions to prevent morbidity associated with ADHD diagnosis.

The proposed study recognizes the high degree of comorbidity with ADHD and the increased risk of a range of adverse outcomes associated with it, especially in the absence of adequate detection, diagnosis, and treatment. By conducting a study in which a full range of diagnoses can be made and by carefully documenting differential diagnosis of similar or related disorders, we can gain a better understanding of the prevalence of ADHD and other disorders in the community and clarify the independent associations of ADHD and other disorders with this range of outcomes—that is, to determine which disorders (or subtypes of disorder) are independently associated with poorer quality of life, increased likelihood of risky behaviors, adverse impact on family life and schools, after controlling for confounding by other correlates. The data collection in Wave 4 and 5 will allow us to track developmental trajectories of co-morbid disorders through later adolescence, which will allow a closer look at factors that become more prevalent with time, such as diagnosis of conditions like depression, risks encountered in dating or motor vehicle operation or educational plans past school, Although findings from this effort will not be directly generalizable past the communities from which the subjects were drawn, data on the community-based prevalence of ADHD, related comorbidities, and the frequency and type of health risk behaviors will assist CDC in better defining the public health impact and burden of the disorder and provide current community-based estimates of ADHD. This information may provide valuable data for health, mental health, and school systems to plan for the most appropriate, effective and efficient services within their resources, and to inform potential public health prevention and intervention strategies.

In light of considerable recent controversy concerning over- or under- diagnosis and treatment of ADHD, comparison of our results to community diagnosis and treatment using state-of-the-art diagnostic tools and recently published standards of practice will contribute substantially to knowing the extent of the problem. Further, given the demonstrated success of a number of treatments, pharmacological, behavioral, cognitive, and relational, our study of barriers to care for those with the disorder should prove important to those who formulate policy and develop programs. This study will enable an assessment of the outcomes of children with ADHD who received and who did not receive treatment, and will provide a view of the quality of care received by these children as they transition into adulthood. It will also further our understanding of treatment effectiveness and health care access

and utilization of youth with ADHD. This is important in helping CDC and practitioners address issues of health disparities and better promote the health, well-being, and quality of life of individuals with ADHD and their families.

Overall, given the magnitude of public concern over the diagnosis and treatment of ADHD, these data are particularly necessary for public health planning. Additionally, these data will substantially increase the Government's knowledge about ADHD in non-clinical populations and may result in the enhanced quality of life for individuals affected by ADHD. The knowledge gained from this study will assist the CDC, NCBDDD, in providing the public and health professionals with the most accurate and up-to-date information concerning ADHD. Without these data, the CDC would be limited in its ability to make the most informed decisions and recommendations concerning treatment, prevention of secondary conditions or risk behaviors, and health care service experience of individuals with ADHD and related comorbidities.

Privacy Impact Assessment

The PLAY study follow-up requires continued updates of personally identifiable information such as mailing addresses, phone numbers, email addresses to enable continued contact with participants. Date of birth, driver's license, education records, and employment status of the youth are necessary to collect to evaluate the relation of age, educational progress, driving status, or employment status on the developmental functioning of youth with or without ADHD.

Because the study collects ongoing information of personally identifiable data as well as potentially sensitive data such as mental health status, substance abuse or delinquency, a Certificate of Confidentiality has been obtained for this study. To increase the protection of respondents' privacy, all assessment data will be identified by study ID only. Personally identifiable data such as names and contact information will be kept separately, and the master list containing personal identifying information and corresponding ID numbers will be stored in a secure location with limited personnel access. See Section A. 10 for more details about data security.

A. 3. Use of Improved Information Technology and Burden Reduction

Where possible, the study sites will use technology to assist in and reduce the time involved for data collection. Only the minimum amount of data necessary will be collected. All data collection forms will be printed on scan-able forms and read with an optical mark reader. Using scan technologies will allow for prompt access to these data and will also have a variety of data quality checks by virtue of using scan-able forms. The scanner and database server will be programmed to reject out-of-range data, and database queries will be written to identify key missing data or inconsistencies.

Participants will be given the option of completing selected assessment instruments either as self-report or per direct interview, depending on their personal preference. Some assessment instruments are always collected via interview due to the complexity of the survey (e.g., the treatment questionnaire). Electronic submission of responses is not included because web-based surveys would not decrease the burden time and might increase potential breach of privacy. The option of in-person interview decreases the likelihood of inaccurate data due to potential reading comprehension issues.

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

Currently there are no data collection activities at the federal level comparable to the proposed data collection. The National Center for Health Statistics supports one question on ADHD in its National Health Interview Survey (OMB # 0920-0214), which is conducted annually. Further, the 2003 National Survey of Children's Health (OMB # 0920-0406) asked families of youth about both a history of ADHD as well as current ADHD medication status. However, these surveys are limited in their utility for assessing the developmental trajectory of ADHD, assessing incidence, and investigating associated

factors, special populations, comorbidity, or health risk behaviors related to ADHD in children. None of these surveys collect continuous data on cohorts of individuals and thus cannot be used to examine developmental trajectories.

Additionally, information on health risk behaviors (those behaviors associated with negative or poor health outcomes) is routinely collected on school populations in the Youth Risk Behavior Survey (YRBS, OMB # 0920-0493) conducted by CDC. However, this surveillance activity is conducted only on adolescents and not on children, and currently cannot be linked to specific mental or behavioral problems in participating youth nor related to factors in elementary school age. The proposed study will continue to collect risk behavior data among a community-based population of school-age youth with and without ADHD across elementary through high school age. In order to ensure comparability with national norms, we will utilize questions from the YRBS where appropriate. Also, since data will be collected longitudinally we can examine the incidence of health risk behaviors over time. These data will be extremely valuable to prevention and intervention planning resulting from the study findings.

As mentioned previously, very few longitudinal community-based samples of children with ADHD exist. The multi-modal treatment study of ADHD (MTA) continues to follow their cohort of youth with ADHD (MTA Cooperative Group, 1999). However, the participants had to meet strict inclusion criteria and likely do not represent average children with ADHD receiving usual community care for ADHD (MTA Cooperative Group, 1999). A recent study by Hinshaw (2006) followed a sample of 11-18 year old girls with ADHD and a matched comparison group for 5 years. While the study contributed important information about the history of ADHD in girls, it was not a community-based sample and results were specific to only one gender. The Pittsburgh ADHD Longitudinal Study (PALS) is an important cohort of 364 youth with ADHD and their probands who were recruited from pediatric clinics and through advertisements. Recent data have been published on the increased risk of alcohol use among youth with ADHD (Molina et al., 2006; Molina et al., 2007) with additional outcomes into adolescence and adulthood forthcoming. However, regional and community variation exists in the diagnosis and treatment of ADHD and it is therefore additional data on a diverse set of community samples is needed in order to characterize the long-term effects of treatments, lack of treatment, and quality of care among youth with ADHD.

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

No small businesses will be involved in this data collection.

A. 6. Consequences of Collecting the Information Less Frequently

Information from parents and youths from the PLAY Collaborative Study will continue to be collected on an annual basis during the 2-year extension of the study period, i.e., Wave 4 and 5. Annual collection of information about diagnoses, symptoms, outcomes, risk factors and health promotion behavior is necessary to document longitudinal trajectories and changes over time. Continuing the annual data collection into Wave 4 and 5 will allow documentation of trajectories and changes into middle and late adolescence. Gathering the data less frequently would prevent the adequate documentation of prevalence of diagnoses, symptoms, outcomes, risk factors and health promotion behavior. Quarterly contact with the participants will be continued to gather information about ADHD treatment and school events that participants otherwise would not be able to remember in detail, and to collect current contact information for retention purposes. Semi-annual assessment of symptoms is also necessary to document changes over time and to maximize accuracy of participants' recall. Any less contact with participants would decrease participation and retention rates and lessen the accuracy of the information gathered. There are no legal obstacles to reducing the burden.

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

This study complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are required.

A. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A draft copy of the Federal Register notice for this data collection effort is included as Attachment B1. The 60 day Federal Register notice citation is FRN 9/24/2009, Volume 74, page 48749.

B. On June 22, 2006, CDC convened an external scientific peer review panel to assess the scientific merit of the PLAY Collaborative Study follow-up proposals. The panel was charged with evaluating the proposals based on the applicants' technical approach, personnel and management plan, and facilities, equipment, and resources. Specifically, the applications were evaluated on (but not limited to) the following aspects:

- Study design and methodology;
- Elaboration of research questions;
- Discussion of any previous data and literature;
- Proposed sample;
- Power Analysis;
- Description of the proposed approach to accomplish the study aims;
- Human subjects compliance, including clarity of informed consent and instructions;
- Frequency of data collection, including proposed assessment measures and their frequency of administration;
- Plans for sample maintenance;
- Plans for ensuring consistent and replicable assessment of the study variables of interest within and across sites during the duration of the study;
- Data management, including plans for ensuring data quality and data security;
- Data analysis;
- Experience and skills of the proposed staff, including appropriate training expertise and expertise in assessing children with ADHD and their families;
- Adequate facilities, equipment, and resources to conduct the proposed work.

In order to maintain the scientific integrity of the external objective review process, the names of the panel members must remain confidential. The panel consisted of nationally renowned experts in the fields of ADHD, epidemiology, and statistics. Panel members were selected to ensure gender, racial/ethnic, and geographic representation. The proposals were deemed to be scientifically sound and worthy of award.

C. Research Planning Meetings – Beginning on September 1, 2006 (the initiation of the project period), the PLAY Study follow-up sites worked with CDC through weekly conference calls to establish a common protocol, including addressing measurement issues. The two sites have worked in collaboration with CDC to review the measures and to resolve site discrepancies. In addition to the conference calls, the National Center on Birth Defects and Developmental Disabilities, Division of Human Development and Disability convened a research planning meeting in Atlanta on October 5, 2006 with representatives from the collaborating research institutions. The purpose of the meeting was to finalize a common study protocol for the PLAY Study follow-up. Throughout the project, biweekly planning calls have been conducted between CDC and the study sites. Such biweekly calls will continue during the requested approval period of July 2010 through July 2013. In addition to participating on the conference calls, the following individuals attended the October 5, 2006 meeting:

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Lorie James, MP.H., Project Manager, Research Associate at University of South Carolina, Norman J. Arnold SPH, University of South Carolina,800 Sumter Street, Columbia, SC 29208, 803-777-1124, Lljames@gwm.sc.edu

Lareissa Stumm, Graduate Assistant, 803-777-7492, University of South Carolina, Norman J. Arnold SPH, University of South Carolina,800 Sumter Street, Columbia, SC 29208 placel@mailbox.sc.edu.

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Melissa Doffing, M.A., Project Manager at Oklahoma University Health Sciences Center, 1100 NE 13th Street, Oklahoma City, OK 73104, 405-271-6824 ext. 42117, melissa-doffing@ouhsc.edu

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Susanna Visser, M.S., Epidemiologist, Child Development Studies Team, DHDD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3008, SVisser@cdc.gov

Camille Smith, M.S., Ed.S., Behavioral Scientist, Child Development Studies Team, DHDD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3007, CSmith@cdc.gov

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Dianne Ochoa, Public Health Analyst, Child Development Studies Team, DHDD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3037, DOchoa@cdc.gov

Alexandra Balaji, Ph.D., Epidemiologic Intelligence Service (EIS) Officer, Child Development Studies Team, DHDD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3099, ABalaji@cdc.gov

Ann Abramowitz, Ph.D., Associate Professor of Psychiatry and Psychology, Emory University, 532 Kilgo Circle, Atlanta, GA 30322 ADHD Clinical Consultant to the Child Development Studies Team, Division of Human Development and Disability (DHDD), NCBDDD/CDC, 404-712-9513, aabramo@emory.edu

Although not in attendance at the Oct. 5, 2006 meeting, the following individuals have participated on conference calls, served as internal consultants and contributors to this project on issues regarding study design, measurements, and data collection methods:

David Bard, M.S., Statistician, University of Oklahoma Health Sciences Center, 1100 NE 13th Street, Oklahoma City, OK 73117, 405-271-6824 ext. 45141, David-Bard@ouhsc.edu

Jeannette Bloomfield, M.S., Public Health Analyst, Child Development Studies Team, CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3003, JBloomfield@cdc.gov

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Throughout 2009, focused research planning meetings were conducted via a series of teleconferences to review and evaluate the existing assessment protocol and to identify any instruments that needed revision or addition to be suitable for the high school age. The proposed protocol resulted from the in depth review on these phone calls. We also consulted with experts on driving and dating violence to identify the best assessment tools for these constructs.

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Corinne Ferdon, Ph.D., Health Scientist, CDC/CCEHIP/NCIPC, 1600 Clifton Road, MS F-64, Atlanta, GA 30333, 770 488 0542

Greta Massetti, Ph.D., Lead Behavioral Scientist, CDC/CCEHIP/NCIPC, 1600 Clifton Road, MS F64, Atlanta, GA 30333, (770) 488-394, gmassetti@cdc.gov

Jennifer Wyatt Kaminski, Ph.D., Behavioral Scientist, Child Development Studies Team, CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333, 404-498-4159, jkaminski@cdc.gov

D. An in-depth portfolio review was conducted in August of 2007 by the National Center on Birth Defects and Developmental Disabilities, Division of Human Development and Disability on the Child Development Studies Team's activities, of which the PLAY study follow-up is a part. The review panel consisted of external independently-selected experts, and their final report concluded that the PLAY study was a scientifically strong project likely to increase knowledge of the prevalence, risk factors and co-morbidities associated with ADHD as well as a relevant and significant contribution to public health.

A. 9. Explanation of Any Payment or Gift to Respondents

In order to ensure subject retention (a critical component of longitudinal studies), modest parent and youth incentives will continue to be utilized to encourage participation. The method for payment of participants for their time and contribution is in the form of cash or gift cards.

Incentives are critical to the study, to improve data quality by maximizing response rates, and due to the complexity of the study design, requiring longitudinal participation and repeat assessment of the specific and unique set of participants who have been participating in the PLAY study. Prior experience with samples of similar nature and with the participants to be enrolled in this study has shown that because of the length of the assessments, especially for parents, and the frequency of data collection, parents and children should be reimbursed for time and effort in order to maximize participation rates. At the South Carolina site, for Wave 1, 293 of 324 participants who were enrolled and invited to the annual assessments also participated, representing a 90% rate of compliance with interviews. These incentives need to be continued for the following waves to maintain a high rate of attendance.

The table below shows the schedule for incentives. A larger amount is provided for the annual interview assessment because it is considerably longer. An incentive is provided both for the parent and the child portion of the interview, because the parent and child portion of the interviews are separate and separate incentives will maximize response rates to both portions of the protocol. The child is given a smaller amount both because of age and because once parents are willing to attend the interviews, incentives are needed to ensure the child's participation in their portion of the interview, but a lesser incentive is considered sufficient. In order to ensure a higher response rate, incentives for the semi-annual phone/mail interviews will be provided to participants in advance of interview completion.

The incentives for parents of children up to middle school are the same as was used for Wave 1-3. A slight increase in incentives for high school and above is proposed. When study participants reach high school age, they may continue to participate either accompanied or unaccompanied by a parent/caregiver. The overall time burden of the annual interviews will increase for participants high school age and older due to the additional surveys items on bullying, dating etc.. Further, in some cases, the participant may have the increased burden of driving to the research offices on his/her own. This age group will be transitioning from living at home to living on their own, and from attending

high school to taking on other major endeavors such as attending college or technical school, joining the military, or obtaining a job. Increasing the incentives for this group, would help defray driving costs and, more importantly, is a central way to incentivize continued participation for both high school age and older participants and their parents. Incentives will continue to be provided in the form of cash for annual in-person assessments and gift cards for quarterly and semi annual assessments via mail.

	Annual Incentive		
Participant	Annual In-person Interview	Semi-Annual Phone/Mail Interview	*Total*
Parent	$50	$25	***$75***
Child	$20	--	***$20***
High School & Older Participants	$50	--	***$50***
Parent of High School & Older Participants	$75	$25	***$100***

In addition to these incentives for the data collection, we will offer an additional incentive for parents who participate in quarterly update phone calls in the form of an annual prize drawing for one $100 prize per site. Teachers who complete rating scales will have their name entered into an annual prize drawing for $500 each time they return a scale.

A. 10. Assurance of Confidentiality Provided to Respondents

Overview: Specific personally identifiable information such as names, addresses, and other contact information are collected by the site for the purpose of maintaining contact with participants throughout the duration of the study. These identifying variables are stored separately from the response data which is identified by study ID only; the master list connecting names and ID numbers is stored in a secure location with limited personnel access. Other potentially identifiable data such as date of birth, driver's license, education records, and employment status of the youth are part of the response set. To protect these data, a number of technical, physical, and administrative safeguards have been put in place to minimize opportunities for inadvertent disclosure of identifiable respondent information. Procedures for data security, the assignment of a unique respondent identification code to each participant, and separation of response data from identifiers (where possible) are described in more detail below.

IRB approval

All research activities for the study will be conducted in accordance to all applicable human subjects regulations (see Attachment E, IRB approvals; Attachments D (consent and assent forms). The current approved IRB protocol includes an extension of data collection through wave 5. An amendment to modify the assessment protocol to add measures for older adolescents is pending. Given the sensitive nature of some the questions (see Section A11) and the collection of identifiable data, a Certificate of Confidentiality (section 301 (d) of Public Health Service Act) was obtained for the study. This

additional level of confidentiality protection increases the likelihood of participants providing valid responses to sensitive questions.

Privacy Impact Assessment Information

A. Privacy Act

The PLAY follow-up has been reviewed by ICRO, who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0136. The collection of personally identifiable information will continue for Waves 4 and 5, thus the impact on participants' privacy is the same.

B. Technical, physical, and administrative safeguards

To protect the confidentiality of records and maintain the privacy of all subjects, the University of South Carolina has developed a detailed security program and plan according to the guidelines provided in the Department of Health and Human Services (DHHS) Information Systems Security Program Policy at http://intranet.hhs.gov/infosec/policies_guides.html.

All information about families included in this study will be kept in files and on databases for which only research staff have access. All study participants have been assigned a unique identification (ID) number at the time of consent that will be maintained throughout the follow-up study. Each form is coded with this unique identifier and without names. The master list containing personal identifying information and corresponding ID numbers will be stored in a secure location with limited personnel access. All data will be collected using coded forms, except for contact information and sheets linking identifiers to code numbers. All other data will be entered using code numbers into data files on password protected computers in locked project offices. In addition, identifying information will be stored in password protected files and in locked filing cabinets. Collected data will be stored in two forms: paper forms and electronic data files. All paper questionnaires are coded with a unique identifier with no names on the form. All completed hardcopy forms will be stored in a locked file and all hardcopy material containing information that is no longer needed will be shredded. All electronic data are stored on a USC Arnold School of Public Health server (see below) or on password protected computers in locked offices. Data will also be collected on coded paper questionnaires or directly entered into password-protected laptop computers in the field or in our offices. Data on laptops are backed-up onto memory keys that are stored in locked offices and data entered with coded identifiers. Data are then transferred to the School server for secure storage and daily back-up.

Paper forms are kept in a locked office and are scanned using Teleform (v9.1) into a database. Scanning is continuously monitored for quality control and correction of scanning errors. The electronic data files are stored on a secure server (see below). Each month, questionnaires are collated by form type and by form version for scanning. The project manager delivers the forms to the scanning center where the forms are stored in locked filing cabinets when they are not being scanned. Teleform is designed to identify questionable characters for correction and to automatically store data in the appropriate format. Scanning center personnel work very closely on quality control measures with the project manager. When scanning is complete, the project manager picks up the forms and files them in locked storage cabinets in a locked space next to the study offices.

The following measures are employed in the USC Arnold School of Public Health server environment:

(1) Unique user id's for individual users.

(2) Passwords must be at least five characters in length.

(3) Passwords must be changed every 180 days.

(4) Access to data directories restricted to userid or group membership.

(5) Servers are located in an isolated secure (locked) room with alarms that connect to university police.

(6) Servers reside on the network behind University firewall.

(7) Virus protection software on all servers.

(8) Daily backup of servers to University data center (UTS).

To further protect confidentiality, access to the data will be restricted with the use of a data bank security system. Users will be required to enter a valid logon ID and password, thus minimizing the possibility of outsider access. Unauthorized users will be denied all access to the data.

Within 30 days after the completion of an assessment (data collection) phase, the study site will submit to the CDC via a secure carrier two electronic copies of all non-identifiable assessment data in SAS format (on compact disc, CD-R). These data sets will be indexed by the unique ID number and will not contain any personal identifying information.

To allow the possibility of further follow up into adulthood by CDC after the completion of the study, participants will be asked for consent to have their identifying contact information transmitted to CDC at the end of the study, so that they may be considered and approached for further studies (See Attachments D1, D3). A master list Those participants who are willing to be approached for further studies will be transmitted to CDC at the completion of the study and will be maintained securely and separately from the data sets.

C. Respondent consent procedures

Participant consent was obtained as part of the enrolment process into the longitudinal follow-up study, at the initial assessment visit for Wave 1. Families who had participated in the interview portion of the original baseline PLAY study (OMB application No. 0920-0584) were invited to participate in the longitudinal follow up. At the beginning of the first assessment visit, written consent was obtained from parents or guardians, and assent from children. Parents were given a copy of the consent form and assent form for their records. At each following assessment contact, participants are presented with another copy of the consent form and reminded of their rights to refuse any portion of the assessments or to withdraw at any time without negative consequences.

The consent form used for enrolment into the longitudinal follow-up study already specified that the study may include five waves of data collection. The consent states “The study is planned for 3 years but may be extended to take 5 years.” (See Attachment D). Additional consent for Wave 4 and 5 will be obtained to inform participants about the current incentive structure and to ask for separate consent to have their identifying information given to CDC to be potentially told about future studies.

The development of the initial study protocol was based on recognizing the intricacies involved in human subject protection procedures, particularly when conducting research with children and adolescents, with regard to privacy and confidentiality. The consent form also clearly specifies all applicable limitations on confidentiality (e.g., mandated reporting of harm to self or others, and child abuse and neglect, parents' access to children's or adolescent’s research data). For mandated reporting, a detailed triage protocol has been developed (See Attachment G). Study staff have been trained on all human subjects rules and regulation for conducting research as well as the triage protocol, and the site project manager periodically reviews all procedures with study staff to ensure that the protocol is followed.

Given the sensitive nature of some the questions (see Section A11) and the collection of identifiable data, a Certificate of Confidentiality (section 301 (d) of Public Health Service Act) was obtained for

the study. This additional level of confidentiality protection increases the likelihood of participants providing valid responses to sensitive questions.

D. Voluntary response and Certificate of Confidentiality

The nature of the data collection is voluntary. All participants were informed at the time of consent that participation is entirely voluntary and that they may both refuse any part of the data collection as well as withdraw at any time, without negative consequences Participants were given the option of participating themselves but refusing consent for their child participate, or refusing consent to collect teacher data. See consent forms, Attachment D. In the consent, participants are also specifically informed of the purpose and intent of the study and of the fact that that de-identified data will be shared with CDC. For all assessments including those planned for Wave 4 and 5, participants are reminded of their rights as human subjects as part of the consent procedures.

Site protocol

The study site has a protocol in place that include provisions for informing children and parents of the confidentiality of responses from children and the limited circumstances under which that confidentiality may and should be breached (e.g., mandated reporting of serious harm to self or others, and child abuse/neglect, based on questions about health risk behaviors and mental health concerns included in the data collection protocol). This protocol includes detailed specific steps to be taken regarding issues concerning:

A. Obtaining informed consent
    a. Informing participants of the nature, treatment, and confidentiality of personal information collected
    b. Attending to potential confidentiality issues such as reporting child abuse and neglect and addressing referral procedures (See Site Triage Protocol, Attachment G)
B. Data security
    a. Data collection, management, and reporting
    b. Data security infrastructure

A. 11. Justification for Sensitive Questions

The data collection for Wave 4 and 5 will include the same constructs as the previously approved data collection for Waves 1-3. The data collection is focused on child mental health and risk behaviors which may be sensitive in nature to participating parents even though not being considered potentially harmful to them or their child (for example, instruments that assess the quality of social life or relationships, such as the Parent Child Relationship Inventory (C11, used in Wave 1-3). Described below are the instruments that contain potentially sensitive questions and a synopsis of the plans for dealing with the sensitive nature of these questions.. As always, participants will be informed that participation in any part of the project is completely voluntary and they may refuse to answer or complete any component of the data collection without penalty.

Potentially Sensitive Data Collections: The data collection will again include questions within the interview that might be considered sensitive.

New potentially sensitive instruments or items: For Wave 4 and 5, we propose to add items and surveys to assess health risk behaviors in high school which may be potentially sensitive

A. Conflict in Adolescent Dating Relationships (Attachment C18):
    a. Youths' sexual behavior

b. Aggressive and violent behavior

B. Olweus Bullying Questionnaire (Attachment C25)

a. Bullying behavior and victimization

C. Additional items for the Health Risk Behavior Survey (Child Report, Attachment C20)

a. Driving rule violations

b. Misuse of prescription medication

Existing potentially sensitive instruments or items: These following sections of the existing interview which will continue to be used for Waves 4 and 5 contain sensitive questions:

A) Health Risk Behavior Survey (Parent and Child Report; see also Attachments C9-10, C19-20,)
   a. Knowledge of the presence of school problems
   b. Knowledge of child's aggressive, violent, or delinquent behavior
   c. Knowledge of youth's use of tobacco
   d. Knowledge of youth's use of illicit drugs
   e. Knowledge of youth's sexual behavior
   f. ADHD medications

B) Demographic Survey (see Attachment C8)
   a. Race, ethnicity, marital status, family relationships, income and educational level

C) Parent Questionnaire on Mental Health (C12)

   a. Parent's history of emotional and/or psychiatric problems, medical diagnoses related to these conditions, and treatments

   b. Child's history of emotional and/or psychiatric problems, medical diagnoses related to these conditions, and treatments

D) Parent Social Isolation Support Questionnaire (C14)

E) DISC-IV (See attachment C30)

   a. Knowledge of mental health diagnoses
   b. Knowledge of the presence of school problems
   c. Knowledge of child's aggressive, violent, or delinquent behavior
   d. ADHD medications

Continued assessment of these data are necessary for Wave 4 and 5. As mentioned previously, children with ADHD are at higher risk for suboptimal educational achievement, delinquent and antisocial behavior, motor vehicle accidents and other injuries, early substance use and/or abuse, early sexual behavior, and a litany of psychiatric comorbidities, compared to children without ADHD (Molina & Pelham, 2003; Rowland, et al., 2002; AACAP, 1997; AAP, 2001). It is therefore necessary to ask questions about these factors because the purpose of the study is to monitor the prevalence of ADHD and comorbidities in this sample, and to better understand the consequences of ADHD on the psychological, emotional, and behavioral well-being of the child across diverse populations and during the course of development into adolescence. Assessing these factors will also allow us to better understand whether negative outcomes associated with ADHD are mediated by increased presence of health risk behaviors.

Adolescent health and health risk behaviors are addressed in the Health Risk Behavior Survey for this segment of the study sample. These include questions about alcohol and drug use for youth in middle school, and more detailed questions about illicit drug use and sexual behavior for youth in high school.

The specific age appropriate questions were taken from the middle and high school versions of the Youth Risk Behavior Survey (YRBS), a survey that has been implemented nationally since 1991 on a biennial basis. The questions about risk behavior allow us to document how children in this sample with and without ADHD compare to national norms, and to examine the specific health risks associated with having ADHD. Motor vehicle accident risk is particularly of importance given the likelihood that children learn to drive during the high school years.

Some of the questions included in the interview concern self-harm or may reveal information about maltreatment, and thus may require further referrals or reporting to authorities. Such questions are included in the Health Risk Behavior Survey, e.g., regarding delinquency and injuries, as well as the Diagnostic Interview Schedule for Children IV e.g., regarding traumatic stress and suicidality. The Parent Questionnaire may also bring to light a need for a mental health referral. The site has extensive experience conducting interviews with potentially sensitive topics and will continue to follow the triage protocol which addresses how responses to these questions will be handled step-by-step, how to determine if follow-up is needed, how it will be conducted, and who will need to be informed. See Attachment G.

A. 12. Estimates of Annualized Burden Hours and Costs

The burden of the proposed data collection on the participants is described in the table below. All estimates for number of respondents take into account non-response or refusal to participate and are based on an 85% rate of response.

Some scales are administered to the entire sample but using different versions depending on the age of the child (i.e., Critical School Events, Health Risk Behavior Survey, MARSH – Self Description Questionnaire, Pediatric Quality of Life, Strengths and Difficulties Questionnaire). For some scales (i.e., Health Risk Behavior Survey and MARSH – Self Description Questionnaire) the time burden is different depending on the age of the respondent.

For these scales with different versions, the overall burden for respondents in each age group was based on the average number of children who would be reaching the specified age group across the three study years. For example, 92 children will be 13 or less years of age in Wave 4, 41 in Wave 5. The extension of the project will be for 3 years, with 2 assessment time points for the annual assessments. Thus, the average number of respondents in this age range who will receive the middle school version of the Health Risk Behavior Survey is 85% of 132 divided by the 3 project years, i.e., 37. Detailed description of how average number of respondents is calculated based on age group can be seen in Attachment F2.

Please note that the Dating Violence Survey and the Youth Demographic Survey will be administered only to children who are age 16 and older.

The number of parents and children in this study differ because in some cases, siblings are included in the study. The expected number of respondents for parent report for each wave is therefore either 267 for forms that parents of siblings only complete once, or 285 for forms that they complete for each sibling separately. Annualized over 3 years, the number of respondents therefore will be 178 for parent self-report forms, and 190 for parent report on children. Only one parent in the family will be asked to complete the forms. See Attachment F2 for details.

Descriptions of each of the survey instruments that are listed in the following burden table can be found in Attachment C2.

Estimated Annualized Burden Hours

Type of Respondent	Survey Instruments	No. of Respondents	No. of Responses/ Respondent	Avg. Burden/ Response in Hours	Total Burden (in hours)
Parent	ADHD Communication and Knowledge *(Attachment C3)*	190	1	10/60	32
Parent	ADHD Treatment, Cost, and Client Satisfaction Questionnaire *(Attachment C4a)*	190	1	10/60	32
Parent	ADHD Treatment Questionnaire *(Attachment C4b)*	190	3	7/60	67
Parent	Brief Impairment Scale *(Attachment C5)*	190	1	4/60	13
Parent	Critical School Events (Middle School) *(Attachment C6)*	37	2	4/60	5
Parent	Critical School Events (High School) *(Attachment C7)*	153	2	4/60	20
Parent	Demographic Survey *(Attachment C8)*	190	1	5/60	16
Parent	Health Risk Behavior Survey (Middle School) 11-13 years *(Attachment C9)*	37	1	18/60	11
Parent	Health Risk Behavior Survey High School, 14+ years *(Attachment C10)*	153	1	22/60	56
Parent	Parent-Child Relationship Inventory *(Attachment C11)*	190	1	15/60	48
Parent	Parents' Mental Health Questionnaire *(Attachment C12)*	178	1	5/60	15
Parent	Quarterly update form *(Attachment C13)*	190	3	1/60	10
Parent	Social Isolation/Support *(Attachment C14)*	178	1	2/60	6
Parent	Strengths and Difficulties Questionnaire (SDQ) *(Attachment C15)*	190	2	3/60	19
Parent	Vanderbilt Parent Rating Scale *(Attachment C16)*	190	2	10/60	63
Child	Brief Sensation Seeking Scale	190	1	1/60	3

	(Attachment C17)				
Child	Conflict in Adolescent Dating Relationships *(Attachment C18)*	153	1	10/60	26
Child	Health Risk Behavior Survey (Middle School) 11-13 years *(Attachment C19)*	37	1	15/60	9
Child	Health Risk Behavior Survey (High School) 14+ years *(Attachment C20)*	153	1	25/60	64
Child	MARSH – Self Description Questionnaire v I, 7-12 years *(Attachment C21)*	15	1	5/60	1
Child	MARSH – Self Description Questionnaire v II, 13-15 years *(Attachment C22)*	90	1	7/60	11
Child	MARSH – Self Description Questionnaire v III 16+ years *(Attachment C23)*	85	1	9/60	13
Child	Social Inventory (High School) 14+ years *(Attachment C24)*	153	1	10/60	26
Child	Olweus Bullying Questionnaire (High School) 14+ years *(Attachment C25)*	153	1	7/60	18
Child	Pediatric Quality of Life Child (8-12) *(Attachment C26)*	15	1	5/60	1
Child	Pediatric Quality of Life Teen (13+) *(Attachment C27)*	175	1	5/60	15
Child	Youth Demographic Survey, 16+ years *(Attachment C28)*	85	1	5/60	7
Teacher	Teacher Survey *(Attachment C29)*	949	1	10/60	158
	Total Grand Total:	190 children 178 parents 949 teachers 1317			**765**

Burden estimates for the surveys were based on reports of average administration by the sites with the participants in the previous PLAY study, with the exception of the Conflict in Adolescent Dating Relationships Inventory where the average administration time was reported by the scale author.

Please note that the ADHD Treatment Quarterly Update and the Quarterly Update Events and Demographics form will be administered quarterly but not at the annual interview, where the longer ADHD Treatment, Cost, and Client Satisfaction Questionnaire, the Critical School Events, and the Demographic Survey are in place.

Per participant: The estimated average annual burden for a parent is 2.5 hours for the annual assessment, 4 minutes for the two quarterly contacts, (which includes the ADHD treatment form and the Quarterly Update Events and Demographics form) and 23 minutes for the semi-annual assessment (which also includes the Critical School Events, Strengths and Difficulties Questionnaire, and Vanderbilt), for a total of 3 hours annual burden per participant. The estimated average annual burden for the child is 2.25 hours. The estimated average annual burden for each teacher is 10 minutes. See also section B2 for further details.

Estimates of annualized cost to respondents

Since this is a voluntary survey the participants will be interviewed outside of their working hours. However, in order to account for opportunity costs the following estimates were computed. Specifically, economic estimated burden was calculated by multiplying the estimated burden hour(s) by the hourly wages for each type of respondent.

Type of Respondent	**Survey Instruments**	**Annual Burden in Hours**	**Average Hourly Rate***	**Respondent Cost**
Parent	ADHD Communication and Knowledge	10/60	$27.50	$4.58
Parent	ADHD Treatment, Cost, and Client Satisfaction Questionnaire	10/60	$27.50	$4.58
Parent	ADHD Treatment Quarterly Update	21/60	$27.50	$9.63
Parent	Brief Impairment Scale	4/60	$27.50	$1.83
Parent	Critical School Events	8/60	$27.50	$3.67
Parent	Demographic Survey	5/60	$27.50	$2.29
Parent	DISC-IV	60/60	$27.50	$27.50
Parent	Health Risk Behavior Survey	22/60	$27.50	$10.08
Parent	Parent-Child Relationship Inventory	15/60	$27.50	$6.86
Parent	Parents' Mental Health Questionnaire	5/60	$27.50	$2.29
Parent	Quarterly Update Events and Demographics	3/60	$27.50	$1.38
Parent	Social Isolation/Support	2/60	$27.50	$0.92
Parent	Strengths and Difficulties Questionnaire	6/60	$27.50	$2.75
Parent	Vanderbilt Parent Rating Scale	20/60	$27.50	$9.16
Total Parent				**$85.50**
Child	Brief Sensation Seeking Scale	1/60	n/a	

Child	Conflict in Adolescent Dating Relationships	10/60	n/a	
Child	DISC-IV	60/60	n/a	
Child	Health Risk Behavior Survey	25/60	n/a	
Child	MARSH – Self Description Questionnaire	9/60	n/a	
Child	Social Inventory	10/60	n/a	
Child	Olweus Bullying Questionnaire	7/60	n/a	
Child	Pediatric Quality of Life	5/60	n/a	
Child	Youth Demographic Survey	5/60	n/a	
Total Child				**n/a**
Teacher	Teacher Survey	10/60	$21.00	**$3.55**

The source for average parent salary was the actual parent report of their annual wages from the baseline PLAY survey. The source for average teacher salary for Oklahoma and South Carolina was the American Federation of Teachers, Annual Survey of State Departments of Education.

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

There are no capital or maintenance costs to respondents.

A. 14. Annualized Cost to the Government

It is anticipated this project will be completed within a three-year period. For each year of the project the annual costs to the government will be about $540,931 (see table below). Of that amount, $353,831 will be awarded to the contractor University of South Carolina. These costs include training site staff, data collection, data management, sample maintenance, and data analyses and reporting.

Federal employee costs include program management, data storage, and analysis.

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC Project Officer (GS-13, .25 FTE)	$32,300
	CDC Co-Principal Investigator (GS-14, .25 FTE)	$42,400
	CDC Co-Principal Investigator (GS-14, .25 FTE)	$34,000
	CDC Research Psychologist (GS-13, .25 FTE)	$31,000
	CDC Behavioral Scientist (GS-13, .05 FTE)	$5,700
	CDC Health Scientist	18,300
	CDC Public Health Analyst (GS-12, .25 FTE)	$23,400
	Subtotal, Direct Costs to the Government	$187,100
	South Carolina Cost Principal Investigator (0.10 FTE) Co-Principal Investigator (0.05 FTE)	 $15,705 $ 9,747 $11,353

	Statistician (0.10 FTE) Statistician (0.05 FTE) Project Manager (0.75 FTE) Project Coordinator (0.5 FTE) Graduate Assistance (1.5 FTE) Tuition Supplement Supplies Participant incentives Postage Travel Indirect costs Total	$5,784 $62,611 $25,475 $40,182 $21,175 $4,453 $48,600 $1,895 $5,206 $101,645 $353.831
	Subtotal, Contracted Services	$353,831
	TOTAL ANNUAL GOVERNMENT COST	**$540,931**

A. 15. Explanation for Program Changes or Adjustments

Data collection for Wave 4 and 5 constitutes a program change due to the revision of the data collection procedures for the youth participants who have reached high school age. The following additional items or surveys will be included in the assessment:

- Conflict in Adolescent Relationship
- Bullying
- Educational aspiration and plans past high school
- Driving safety
- Social media use
- Misuse of prescription medication
- Social Inventory: networking, relationships, and competence
- Self-efficacy for ADHD and medication use

The educational aspiration questions will be added to the Youth Demographic Survey. The Conflict in Adolescent Relationship, Olweus Bullying Questionnaire, and Social Inventory will be in separate survey forms. The other items will be added to the Health Risk Behavior Survey, High School version. See Attachment C2 for details on added instruments.

Burden:

The overall annual burden estimate on the individual youth participant of high school age increases by about 15 minutes due to the addition of the new instruments. The total burden of this data collection has changed because the Wave 4 and 5 data will only be collected for South Carolina. The Oklahoma site was not successful in retaining sufficient participants to warrant continued data collection. The burden is now calculated based on the current active participant in South Carolina.

A. 16. Plans for Tabulation and Publication and Project Time Schedule

	Site Activity

Phase 1 1 Month After OMB Approval	Train PLAY staff on assessment protocol changes
Phase 2-7 Months 2-36 After OMB Approval	Maintain compliance with IRB and OMB regulations Schedule assessment visits Mail surveys prior to scheduled visit Conduct interviews Conduct semi-annual survey updates Maintain quarterly contact with participants Enter and clean data for submission to CDC Submit data to CDC
Phase 7, 9-12 Months 37-65 After OMB Approval	Maintain compliance with IRB and OMB regulations Schedule assessment visits Mail surveys prior to scheduled visit Conduct interviews Conduct semi-annual survey updates Maintain quarterly contact with participants Enter and clean data for submission to CDC Submit data to CDC
Phase 8 Months 66-67 After OMB Approval	Enter and clean data for submission to CDC Submit final data to CDC Finalize data analysis Prepare and submit final report

Analysis Plan:

Approach

Data cleaning and psychometric assessment of all measures will precede the model building and estimation procedures. Internal consistency of scales and indices will be checked. Invariance of model parameters will be tested for the differing data collection settings (i.e., mail versus telephone); failure of invariance will prompt covariate control of additive variance components or, worse-case scenario, separate unconstrained parameter estimates for modeling follow up data across the collection techniques (e.g., separate models for mail- and phone-conducted follow-up). Outcome distributions will be modeled as continuous, ordered categorical, censored, binary, or counts, as measures and data deem necessary. Key bivariate relationships will be checked for non-linearity in order to identify possible non-linear relationships that may need to be modeled. Robust standard errors and chi-square goodness of fit statistics will be relied on for inferential conclusions. Inspection of sample distributions will largely determine the exact tests/assumptions used for analyses. As a general analytic approach, more saturated models (i.e., including all relevant predictors) will be explored first, with terms that fail to contribute dropped in order to arrive at a final reduced model.

Because of the stratified (school districts) cluster (schools) sampling design of the original PLAY study, all analyses below will attempt to control for the potential bias of unequal probability sampling of cases within schools (and the reliant invariant unequal probability sampling of controls). Analyses will therefore be run with and without sampling weights to assess the impact of the sampling design on parameters and hypothesis testing. As Asparouhov (2006) points out, when sampling approaches non-informativeness, i.e., the probability of selection and the outcome are conditionally independent given

observed and modeled covariates, use of weights becomes inefficient and less powerful. By including major predictors of sampling probability (e.g., cluster size, cluster random intercepts, case/control status, age, gender, and race) in all models, we hope to minimize the need for weighted analysis (see Korn & Graubard, 1991); however, we choose to rely on the informativeness *t*-test criteria of Asparouhov (2006) for our final decision.

Broadly speaking, two types of expected findings underlie the earmarked longitudinal investigations: those evidencing change in outcomes over time and those evidencing stability or no change over time. Within each category of expected findings, we can further subdivide the analyses into those concerned with count/frequency, categorical, censored, or continuous outcomes. Finally, all analyses are nested under either group-comparisons of or single-group characterizations of outcome trajectories.

Adoption of the recommended non-invariant weighting method and the 6-step procedure for pursuing either pseudo maximum likelihood (PML) estimation for weighted single-level models or multilevel PML for two-level models may be applied, as described by Asparouhov (In press, 2006). Constructed models may be fit within the general latent variable modeling framework (B. Muthén, 2002) of Mplus version 4.0 (L. K. Muthén & Muthén, 2006). Further, some outcomes that appear more amenable to event history modeling will be analyzed using continuous-time Cox frailty regression models that allow both individual-level and cluster-level prediction of proportional hazard changes. Additionally, continuous-time survival mixture models will be explored, with hypothesis-generation goals in mind, allowing unobserved heterogeneity in baseline hazards to be predicted by latent classes. These survival models will also compare parametric baseline hazards and estimation will use the profile likelihood method. See (Asparouhov, 2006), for specification details.

Follow-up data collected from the families of selected PLAY study children will be analyzed in accordance with the following research questions and analytic plan. The instruments used to assess the constructs in each research question explained below are listed and described in Attachments C1 and C2, respectively.

Research Question A. What is the nature of community care diagnosis and treatment patterns for youth with and without ADHD as determined by the case definition in the PLAY Study?

Weighted prevalence of community diagnosis of ADHD will be calculated following the completion of each annual diagnostic interview and in accordance with the PLAY study case definition. Incidence rates may be estimated among the low screen comparison groups. In addition to ADHD, other outcome variables will be considered. In particular, we will evaluate usual community care treatment such as treatment modalities, compliance, and changes in care patterns over time; utilization of non-pharmacological treatment services, including behavioral interventions, mental health counseling, and other medical services; utilization of special education or remedial services. Estimates of rates, means, standard errors, and 95% confidence intervals will be generated by using SAS/SUDAAN and STATA Software.

Research Question B. What is the long-term trajectory of ADHD symptoms and impairments associated with ADHD symptoms among the PLAY Study participants?

We will consider two outcomes of interest: DSM-IV TR symptom counts and impairment level of endorsed symptoms. Both will be considered as continuous outcomes. Children will be observed repeatedly over time. Although we expect to observe unbalanced and mistimed measurements, the longitudinal information provided by the repeated measures will be fully exploited. The long-term trajectory will be modeled as a function of time. Initially, the trend over time of the outcome variables will be modeled by means of cubic splines. Departure from linearity will then be tested and, if not significant, a linear relationship will be assumed. The potential correlation within school and within sex/screening status will be accounted for by introducing random effects in mixed-effects models.

Compound symmetry will be assumed as the initial correlation structure. Also, the within child correlations will be modeled by introducing random intercepts and slopes for the variable time. In addition to the estimates about the trend over time, the model will allow us to estimate the variance of the random intercepts, the variance of the random slopes, the correlation among the random intercepts and slopes, and the proportions of children who will have measures within any range of values. Further, the use of random effects instead of fixed effects will improve the precision of the estimates.

Research Question C. Persistence of ADHD symptoms into adolescence

At the end of the follow-up period, we will be able to evaluate the persistence of symptoms across the entire follow-up period. We will consider symptom count and associated impairment, educational achievement/failure, peer and family relations, and quality of life. We will model the probability of ADHD symptoms at the end of follow-up as a function of the occurrence and persistence of symptoms during the earlier years, while adjusting for potential confounding introduced by socio-demographic and other characteristics of the children and their parents. We will use logistic regression models. To account for the potential correlation within school and within sex/screening status, we will include nested random effects in mixed-effects models.

Research Question D. How are youth with ADHD versus those without ADHD different in rates of psychiatric comorbidity, health risk behaviors, health promotion behaviors, and health status?

We will consider the following events: adverse outcomes (harm from injuries, suicidal behaviors, and aggressive acts), early substance use, substance abuse, substance dependence, delinquent behaviors, psychopathology (i.e., non-ADHD psychiatric disorders), teen pregnancy or paternity and sexual health, health status and indicators of healthy development (e.g., normative height, weight). We will model the hazard rate for the time to each of the events of interest separately. We will use proportional hazard models. Similarly to what we described for Research Question B, the potential within school and within sex-by-screening status correlation will be accounted for by introducing random (best know in proportional hazard models as “frailty”) effects. The comparison between youth with ADHD and those without ADHD will be estimated and tested by introducing a binary variable (0 = No ADHD, 1 = ADHD). The assumption of proportionality of the hazard functions will be evaluated. If proven unreasonable, stratified proportional hazard models will be used.

Research Question E. What are the correlates of obtaining (or not obtaining) appropriate and adequate treatment and educational services for ADHD and/or comorbid conditions?

We will consider the following as potential predictors of not obtaining appropriate and adequate treatment and educational services for ADHD and/or comorbid conditions: access barriers, coordination, and insurance status, parent/child characteristics (e.g., socio-demographics, attitudes, knowledge, cultural factors), parental/child perceived quality of community care, parental/child perceived and real benefits associated with treatment outcomes. These potential predictors can be selected by using model selection.

Research Question F. How do certain predictors of interest affect different non-ADHD psychiatric disorders and what are the quantitative direct and indirect effects of these predictors on these behaviors?

We are interested in finding whether a certain predictor of interest (e.g. the relationship of contextual risk and protective factors, adjusted for other covariates, to behavior problems (e.g. aggressive acts) after estimating the size of both its direct and indirect effect on behavior. These dimensions are important since they may affect children’s school performance even in children without ADHD. To do this, we will use path analysis, a special case of structural equation modeling (SEM), which tests the fit of the correlation matrix against two or more casual models. In path analysis, a regression can be done

for each variable in the model (in our case, the continuous or categorical behavior outcomes) as dependent on others that the model indicates are causes. When the model has two or more casual variables (e.g. parent's education and ADHD, plus covariates), path coefficients are partial regression coefficients that measure the extent of effect of one variable on another in the path model controlling for other prior variables. Direct and indirect effects can be decomposed via path coefficients by using Mplus software.

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

N/A. OMB expiration date will be displayed.

A. 18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions applied to this data collection.