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Supporting Statement

for

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

Primary Contact:
Ruth Perou, PhD
Child Development Studies Team Leader
Division of Human Development and Disability
NCBDDD
CDC
MS E-88
1600 Clifton Road
Atlanta, GA 30333
404-498-3005
404-498-3050 (fax)
rperou@cdc.gov

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This data collection activity is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241; Attachment A1). The proposed study is also consistent with the aims of the Children's Health Act of 2000 (Attachment A2) which mandates 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.

Attention-Deficit/Hyperactivity Disorder 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 will now be invited to participate in this proposed longitudinal follow up study, the PLAY study follow-up. 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. The 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.

A.2. Purpose and Use of the Information

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 follow-up assessment. It will also provide data on baseline variables that can predict poor outcomes in adolescence. 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. 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. It will also further our understanding of treatment effectiveness and health care access and utilization of children 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.

A.3. Use of 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. In South Carolina all data collection forms will be printed on scan-able forms and read with an optical mark reader (Oklahoma currently does not have this same technology available). 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. Once scanned, data will be uploaded to a secure Structured Query Language (SQL) database server. The server is backed up remotely on a regular basis. Access to the database tables will be login and password protected, and identifying information will be stored in separate tables with access limited to the principal investigators and key research team staff.

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.

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. The proposed study will collect risk behavior data on an age group not yet assessed and among a community-based population of school-age children with and without ADHD. In order to ensure comparability with national norms, where appropriate we will utilize questions from the YRBS. Also, since data will be collected longitudinally we can examine the incidence of health risk behaviors. 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. There is limited information on long-term effects of treatments, lack of treatment, and quality of care in community-based samples of children with ADHD, emphasizing the public health importance of longitudinal research in this area.

Rationale for instrument selection:

Although existing ADHD studies cannot be used or modified to meet our agency's needs, we propose to use existing data collection instruments to build off of the work that has already been established. When feasible, we included data collection instruments that were used in the previous PLAY (OMB No. 0920-0584) baseline assessment (i.e., Diagnostic Interview Schedule for Children IV (DISC-IV), Health Risk Behavior Survey, SDQ, VADTRS, ADHD Treatment and Satisfaction, ADHD Communication and Knowledge, Critical School Events, Demographic Survey, Marsh SDQ, Parent-Child Relationship Inventory, PedsQL, Parent Mental Health form). Further, we included some data collection instruments that the South Carolina and Oklahoma sites had previously used in studies with similar populations including children with ADHD (i.e., Brief Sensation Seeking Scale, Critical School Events, Kaufman Brief Intelligence Scale, Social Isolation/Support). We also selected other data collection instruments that are similar to measures that had been used with prior studies, but have superior psychometrics or are more widely used in research (i.e., Brief Impairment Scale and IPPA/PIML).

A description of the proposed data collection instruments can be found in Attachment B2. We selected the proposed instruments specifically to address the main research questions of the study as delineated in Section A16. The specific constructs that are measured by each instrument and their relevance to the research question are delineated in Attachment B1. At times we made modifications to existing data collection instruments; these modifications are clearly delineated

in Attachment B1 and are highlighted on the instruments themselves. Whenever possible, we selected items from existing surveys (e.g., additional items from the YRBS, NSCH) so that we can compare the results to nationally representative samples. Some items were also added from other studies of ADHD populations (e.g., a question about diverting ADHD medication). The source of each question that was modified or added is identified in Attachment B1.

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

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

Information from parents and youths from the PLAY Collaborative Study will be collected on an annual basis during the 3-year study period. Annual collection of information about diagnoses, symptoms, outcomes, risk factors and health promotion behavior is necessary to document longitudinal trajectories and changes over time. 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 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 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.

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 copy of the Federal Register notice for this data collection effort is included as Attachment A3 (*Federal Register: May 18, 2006 in vol. 71, p. 28867-28868)*. No public comments were received.

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. In addition to participating on the conference calls, the following individuals attended the October 5, 2006 meeting:

Robert McKeown, Ph.D., Principal Investigator at University of South Carolina, Department of Epidemiology and Biostatistics, Norman J. Arnold SPH, University of South Carolina,800 Sumter Street, Columbia, SC 29208, 803-777-6220, rmckeown@gwm.sc.edu

Lorie James, MPH, 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.

Mark Wolraich, M.D., Principal Investigator at Oklahoma University Health Sciences Center, CMRI/Shaun Walters Professor of Pediatrics, Child Study Center, 1100 NE 13th Street, Oklahoma City, OK 73104, 405-271-6824 ext. 45124, mark-wolraich@ouhsc.edu

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

Ruth Perou, Ph.D., Team Leader, Research Psychologist, Child Development Studies Team, DHDD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333404-498-3005, RPerou@cdc.gov

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

Angelika H. Claussen, Ph.D., Research Psychologist, Child Development Studies Team, DHDD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3557, AClaussen@cdc.gov

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:

Steven Cuffe, M.D., Co-investigator at University of South Carolina, Norman J. Arnold SPH, University of South Carolina,800 Sumter Street, Columbia, SC 29208, 803-777-7353, cuffe-steven@sc.edu

Barbara Neas, Ph.D., Biostatistician/Epidemiologist at Oklahoma University Health Sciences Center, College of Public Health, 801 NE 13th St, CHB-309, Oklahoma City, OK 73104, 405-271-2229 ext. 48067, barbara-neas@ouhsc.edu

Owen Devine, Ph.D., Statistician, OD/NCBDDD/CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333, 404-498-3073, ODevine@cdc.gov

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

Melody Johnson Morales, Ph.D., Behavioral Scientist, Child Development Studies Team, CDC, 1600 Clifton Road, MS E-88, Atlanta, GA 30333 404-498-3065, MMorales1@cdc.gov

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 be utilized at both sites to encourage participation. The method for payment of participants for their time and contribution will 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 were already part of the PLAY baseline interviews. 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, investigators have conducted longitudinal research on adolescent depression in another school district. They were able to achieve retention rates of 85% after six years of follow-up for nearly 600 recruited youth and their families with such an incentive schedule.

The table below shows the schedule for incentives. Incentive rates were based on the experience and resulting expectations of the participants in the initial baseline study. 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. For the prior PLAY study incentives were provided in the form of WalMart gift cards and were well received. For the current study, participants may be offered a choice of gift cards from different retailers or cash.

	Annual Incentive		
Participant	Annual In-person Interview	Semi-Annual Phone/Mail Interview	*Total*
Parent	$50	$25	***$75***
Child	$20	--	***$20***

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 Participants

The CDC Privacy Officer has reviewed this submission and determined that the Privacy Act applies. The applicable Privacy Act system notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. Although personally identifiable information will be collected and maintained by the contracted research sites for this longitudinal follow-up study, a number of 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.

All research activities for the study will be conducted in accordance to all applicable human subjects regulations (see Attachment C, IRB approvals; Attachments D (consent and assent forms for the Oklahoma site) and Attachment E, (consent and assent forms for the South Carolina site). 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) will be obtained for the study and is currently being processed. This additional level of confidentiality protection will increase the likelihood of participants providing valid responses to sensitive questions.

Both sites have protocols 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). These protocols include 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 Protocols, Attachments H1 and H2)

B. Data security
    a. Data collection, management, and reporting
    b. Data security infrastructure

Human Subjects

An important consideration of this proposed ADHD follow-up study is the adequate protection of human subjects with regard to privacy and confidentiality. We recognize the intricacies involved in human subject protection procedures, particularly when conducting research with children and adolescents. The investigators conducting this research will take all possible steps to

safeguard confidentiality (to the extent allowed by law) and 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) will be clearly explained (and provided in written form) to participants (see Attachments D and E for consent forms). Please note that once the Certificate of Confidentiality is granted, CDC's preferred confidentiality advisement language will be incorporated into all consent documents (see Attachment F, Agreement to add CDC's preferred confidentiality language).

Step by step procedures have been developed to determine in which cases parents should be informed of high risk behaviors reported by their children due to the potential of self-harm, in addition to reporting procedures in cases of reported abuse or neglect (See Attachments H1 and H2). This study does not have an intention to treat design. A significant number of children in the study have diagnosed conditions and are concurrently receiving medical treatment. Some parents may have anxiety about their children's behavior, functioning or emotional well-being. Further, during the interview process, parents or children may report problems and concerns with the treatments that they are receiving. When appropriate, the research assistant will advise the participant to speak with their physician immediately or to go to the emergency room. If the situation does not require emergency attention, the research assistant will encourage the participant to consult with their physician. Serious events will be immediately reported to the principal investigator who will contact the participant to clarify the significance of the serious event and to encourage obtaining timely help if needed. Further, when appropriate, referrals to community health care providers will be offered to participants. All procedures will be in compliance with IRB/Human Subjects regulations.

Data Security

To protect the confidentiality of records and maintain the privacy of all subjects, each study site 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 will be assigned a unique identification (ID) number at the time of consent. The master list containing personal identifying information and corresponding ID numbers will be stored in a secure location with limited personnel access. This provision applies to all study locations. Collected data will be stored in paper forms and electronic data files. 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 will be stored on secured servers. 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 sites 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.

More detailed site-specific information on data security infrastructure is described below.

A. Oklahoma

Once participants provide consent, they will be assigned an identification number. Two files will be maintained for the study. The first file is a statistical data file, which will have all of the interview data, test results, and other statistical information arranged for each subject but identified only by the research number assigned to each child. The information will be maintained in computer files. The second file is a master list that will have the child's name and the research number that was assigned to the particular child with the family contact information and a log of all of the contacts made or attempted with the family. This list will be maintained in a separate database. Only the investigators and research staff will have access to this file. After completion of the interviews and testing, all identifying information on a subject will be separated from the statistical data; the only identifiers available on the statistical records, which are to be maintained on the computer, will be a research number. At 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. At all times during the course of the investigation, only the investigators and their designated associates will have access to this identification file.

The Child Study Center (CSC) at the University of Oklahoma Health Sciences Center is a fully client-server networked environment with a range of on-line services including e-mail, remote backup, database applications, data analysis applications (SPSS, SAS, LISREL, HLM, etc.), document servers, on-line access to library search services, and internet access. All equipment and applications are Y2K compliant. The Child Study Center has 86 networked PCs, including a database server. Data acquired for this project would be centrally stored on the database server running Microsoft SQL 7.0, allowing for multiple user access and data entry with security control. The server is fault tolerant (dual processors, mirrored drives, uninterrupted power source) and incrementally backed up daily with weekly off-site tape backups which are stored in a fire proof safe.

B. South Carolina

Once participants provide consent, they will be assigned a unique identification number. Each form is coded with this unique identifier and without names. 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 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). 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).

A.11. Justification for Sensitive Questions

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 (B12) and the Inventory of Parent and Peer Attachment (B33)). 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. Most of these data were already collected in the baseline assessment of the prior PLAY study (OMB application No. 0920-0584), and will now be collected annually. 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: There are questions within the interview that might be considered sensitive. Particularly, these following sections contain sensitive questions:

A) Health Risk Behavior Survey (Parent and Child Report; see also Attachments B9-13, B17-20, B23-25)
   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 B8)
   a. Race, ethnicity, marital status, family relationships, income and educational level

C) Parent Questionnaire (B13)

   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 (B18)

E) DISC-IV (See attachment B36)

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

As mentioned previously, children with ADHD are at higher risk for suboptimal educational achievement, delinquent and antisocial behavior, 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.

Given that the study participants in the proposed PLAY follow-up study will now include adolescents, age appropriate questions relevant to adolescent health and health risk behaviors were added to 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 are 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. Adding these age appropriate questions about risk behavior will 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.

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. Both sites have extensive experience conducting interviews with potentially sensitive topics and have developed a triage protocol to address how responses to these questions will be handled step-by-step, to determine if follow-up is needed, how it will be conducted, and who will need to be informed. See Attachments H1 and H2 for site triage protocols.

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 will be 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, People in My Life/Inventory of Parent and Peer Attachment, Pediatric Quality of Life, Strengths and Difficulties Questionnaire). For some scales (i.e., Health Risk Behavior Survey, MARSH – Self Description Questionnaire, and People in My Life) 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, 329 children will be 10 or less years of age in the first year, 177 in the second year, and 69 in the third year. Thus, the average number of respondents in this age range who will receive the elementary version of the Health Risk Behavior Survey is 85% of 192, i.e., 163. Detailed description of how average number of respondents is calculated based on age group can be seen in Attachment G2.

Please note that the Brief Sensation Scale will only be administered to a subset of children, specifically, those who are age 11 and older, the Youth Demographic Survey will be administered only to children who are age 16 and older, and the child version of the DISC-IV interview will be administered only to children who are 9+ years of age.

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 is therefore either 892 for forms that parents of siblings only complete once, or 961 for forms that they complete for each sibling separately. Only one parent in the family will be asked to complete the forms. See Attachment G2 for details.

The number of teachers who respond will change according to age. Elementary children (192 children in the sample) are taught by one primary teacher who will be asked to complete the survey. In middle and high school, children are not taught by a primary teacher but will be interacting with multiple teachers during the school day. To obtain an accurate observation of the child's behavior for children in middle and high school (939), all academic teachers will be asked to complete a survey, on average, 5 per child. This brings the total of potential respondents to 85% of 4887, i.e., 4154 teachers. See Attachment G2 for details.

Descriptions of each of the survey instruments that are listed in the following burden table can be found in Attachment B2.

A.12 – 1 Estimates of 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 B3)*	961	1	10/60	160
Parent	ADHD Treatment, Cost, and Client Satisfaction Questionnaire *(Attachment B4a)*	961	1	10/60	160
Parent	ADHD Treatment Quarterly Update *(Attachment B4b)*	961	3	3/60	144
Parent	Brief Impairment Scale *(Attachment B5)*	961	1	4/60	64

Parent	Critical School Events (elementary, middle) *(Attachment B6)*	823	2	4/60	110
Parent	Critical School Events (high school) *(Attachment B7)*	138	2	4/60	18
Parent	Demographic Survey *(Attachment B8)*	961	1	5/60	80
Parent	DISC-IV (Attachment B36)	961	1	20/60	320
Parent	Health Risk Behavior Survey (Elementary) 7-10 years *(Attachment B9)*	163	1	16/60	43
Parent	Health Risk Behavior Survey (Middle School) 11-13 years *(Attachment B10)*	412	1	18/60	124
Parent	Health Risk Behavior Survey (High School)14+ years *(Attachment B11)*	386	1	22/60	142
Parent	Parent-Child Relationship Inventory *(Attachment B12)*	961	1	15/60	240
Parent	Parents' Questionnaire (Mental Health) *(Attachment B13)*	892	1	5/60	74
Parent	Quarterly Update Events and Demographics *(Attachment B17)*	961	3	1/60	48
Parent	Social Isolation/Support *(Attachment B18)*	892	1	2/60	30
Parent	Strengths and Difficulties Questionnaire 4-10 *(Attachment B19)*	163	2	3/60	16
Parent	Strengths and Difficulties Questionnaire 11-17 *(Attachment B20)*	798	2	3/60	80
Parent	Vanderbilt Parent Rating Scale *(Attachment B21)*	961	2	10/60	320
Child	Brief Sensation Seeking Scale (11+ years only) *(Attachment B22)*	798	1	1/60	13
Child	DISC-IV (Attachment B36)	888	1	30/60	444

Child	Health Risk Behavior Survey (Elementary) 7-10 years *(Attachment B23)*	163	1	20/60	54
Child	Health Risk Behavior Survey (Middle School) 11-13 years *(Attachment B24)*	412	1	25/60	172
Child	Health Risk Behavior Survey (High School)14+ years *(Attachment B25)*	386	1	30/60	193
Child	MARSH – Self Description Questionnaire v I, 7-12 years *(Attachment B26)*	426	1	15/60	107
Child	MARSH – Self Description Questionnaire v II, 13-15 years *(Attachment B27)*	398	1	20/60	133
Child	MARSH – Self Description Questionnaire v III 16+ years *(Attachment B28)*	138	1	20/60	46
Child	Pediatric Quality of Life Young Child *(Attachment B29)*	5	1	5/60	1
Child	Pediatric Quality of Life Child *(Attachment B30)*	421	1	5/60	35
Child	Pediatric Quality of Life Teen *(Attachment B31)*	536	1	5/60	45
Child	People In My Life *(Attachment B32)*	426	1	15/60	107
Child	People In My Life/Inventory of Parent and Peer Attachment *(Attachment B33)*	536	1	22/60	197
Child	Youth Demographic Survey, 16+ years only *(Attachment B34)*	138	1	1/60	2
Teacher	Teacher Survey *(Attachment B35)*	4154	1	10/60	692

Total:		961 children 892 parents 4154 teachers			**4414**

Burden estimates for the surveys were based on reports of average administration by the sites with the participants in the previous PLAY study or in other studies the researchers had conducted with similar populations, with the exception of the People in My Life/Inventory of Parent and Peer Attachment 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 hours. The estimated average annual burden for each teacher is 10 minutes. See also section B2 for further details.

A.12 – 2 <u>Annualized Cost to Respondents</u>

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	$17.50	$2.92
Parent	ADHD Treatment, Cost, and Client Satisfaction Questionnaire	10/60	$17.50	$2.92
Parent	ADHD Treatment Quarterly Update	9/60	$17.50	$2.63
Parent	Brief Impairment Scale	4/60	$17.50	$1.17
Parent	Critical School Events	8/60	$17.50	$2.34
Parent	Demographic Survey	5/60	$17.50	$1.46
Parent	DISC-IV	60/60	$17.50	$17.50
Parent	Health Risk Behavior Survey	18/60	$17.50	$5.26
Parent	Parent-Child Relationship Inventory	15/60	$17.50	$4.38

Parent	Parents' Mental Health Questionnaire	5/60	$17.50	$1.46
Parent	Quarterly Update Events and Demographics	3/60	$17.50	$0.88
Parent	Social Isolation/Support	2/60	$17.50	$0.58
Parent	Strengths and Difficulties Questionnaire	6/60	$17.50	$1.75
Parent	Vanderbilt Parent Rating Scale	20/60	$17.50	$5.83
Total Parent				**$51.08**
Child	Brief Sensation Seeking Scale	1/60	n/a	
Child	DISC-IV	60/60	n/a	
Child	Health Risk Behavior Survey	30/60	n/a	
Child	MARSH – Self Description Questionnaire	15/60	n/a	
Child	Pediatric Quality of Life	5/60	n/a	
Child	People In My Life	20/60	n/a	
Child	Youth Demographic Survey	1/60	n/a	
Total Child				**n/a**
Teacher	Teacher Survey	10/60	$18.00	**$3.00**

* Averaged across sites

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 Recordkeepers

There are no capital or maintenance costs to respondents.

A.14. Annualized Cost to the Federal 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 $766,451 (see table below). Of that amount, $610,951 will be awarded to two contractors, Oklahoma, and 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	CDC Project Officer (GS-13, .25 FTE)	$31,000

Government		
	CDC Co-Principal Investigator (GS-14, .25 FTE)	$37,500
	CDC Co-Principal Investigator (GS-14, .25 FTE)	$31,000
	CDC Behavioral Scientist (GS-13, .25 FTE)	$31,000
	CDC Behavioral Scientist (GS-13, .05 FTE)	$5,000
	CDC Public Health Analyst (GS-12, .25 FTE)	$20,000
	Subtotal, Direct Costs to the Government	$155,500
Contractor and Other Expenses	***Oklahoma Site Cost***	
	Principal Investigator (0.10 FTE)	$25,181
	Statistician (0.05 FTE)	$5,372
	Project Director (.85 FTE)	$55,799
	Research Assistance (.85 FTE)	$28,539
	Research Technician (.67 FTE)	$18,716
	Research Technician (.30 FTE)	$ 8,380
	Accounting (0.01 FTE)	$2,149
	Supplies (office supplies, mailing materials, etc.)	$11,500
	Travel	$15,000
	Participant incentives	$38,000
	Postage/FedEx	$2,200
	Printing	$500
	Phone	$1,500
	Indirect costs	$98,969
	Total	$311,805
	South Carolina Cost	
	Principal Investigator (0.10 FTE)	$14,842
	Co-Principal Investigator (0.05 FTE)	$ 9,187
	Statistician (0.10 FTE)	$10,738
	Statistician (0.05 FTE)	$4,170
	Project Manager (0.75 FTE)	$44,391
	Project Coordinator (0.5 FTE)	$24,200
	Graduate Assistance (1.5 FTE)	$22,725
	Tuition Supplement	$10,500
	Supplies	$11,780
	Participant incentives	$50,000
	Postage	$2,340
	Travel	$6,075
	Indirect costs	$88,198
	Total	$299,146
	Subtotal, Contracted Services	$610,951
	TOTAL COST TO THE GOVERNMENT	**$766,451**

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

	Site Activity
Phase 1 1 Month After OMB Approval	Hire and train PLAY staff
Phase 2-7 Months 2-36 After OMB Approval	Maintain compliance with IRB and OMB regulations Recontact and reconsent former participants for current Phase 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 36-42 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 B1 and B2, 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.