B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The cohort for the PLAY study follow-up will be comprised of participants from 6 school districts who were invited and completed the baseline interview of the PLAY study. Youth who were invited to participate in the baseline interview were sampled from the pool of elementary-aged youth screened by their teachers and parents.

Of those with screening information, all children who either screened high on ADHD risk based on the teacher report, or were identified by parents as being diagnosed and/or medicated for ADHD, were invited for the baseline interview portion of the PLAY study. For a control group, the sample of children at low risk for ADHD was first stratified by gender and then cases were sampled proportional to the gender distribution of the high risk group. Design weights were generated for participants of the interview phase of the PLAY sample such that study findings using this weighted sample may be generalized to the school districts from which the youth were sampled.

Of the 2154 youth invited in SC and 3,691 youth invited in OK, 481 and 650 youth completed the baseline interview in South Carolina and Oklahoma, respectively. Thus the cohort sample will be comprised of approximately 1131 youth and their families (SC: 133 high ADHD screen, 348 low ADHD screen; OK: 375 high ADHD screen, 126 low ADHD screen, 14 Tic only; interviewing is still being conducted at that site). Descriptive comparisons indicate that responding families differed somewhat from non-responding families in that significantly more African-American families in SC and significantly more Hispanic families in OK declined to participate in the baseline PLAY interview. The impact of this potential bias may be minimized by incorporating a non-response weight into the existing design weights prior to analysis of these cohort data.

All participants in the baseline interview phase of the PLAY study are eligible for the present study and will be invited to participate. Based on the experiences of our principal investigators with other longitudinal studies, we expect to retain 85% of the participants throughout the three-year study period. For the present follow-up study, we will estimate changes in prevalence over time as well as incidence of ADHD and co-morbid conditions within the control group.

Contact information on the PLAY study cohort was collected a maximum of 3 years ago (with some participants being contacted within the last year). All participants of the interview phase of the PLAY study will be contacted and invited to participate in the follow-up assessments. The assessment schedule will include brief quarterly contacts to obtain updated contact information. Because baseline data has already been collected for these families, any differences between families who choose to participate in the follow up study and those who do not choose to participate will be statistically analyzed.

A detailed break down of respondents by site, including parents, teachers, and children in different age groups can be seen in Attachment G2.

B.2. Procedures for the Collection of Information

Design:

The proposed project is a cohort study. The case-status variable (ADHD vs. not ADHD) will be treated as a risk factor for later developmental changes as opposed to a dependent variable modeling approach appropriate for a traditional case-control design. In this situation, case status will be treated as a fixed covariate and the probabilities of interest will involve developmental outcomes conditional on case status (i.e., probability, as well as, magnitude of change in longitudinal outcome given case status). The models proposed allow us to explore multivariate developmental change contingent on case status through the incorporation of bivariate, trivariate, etc., latent growth models or latent dynamic difference models (see McArdle, 2006).

Data Collection Procedures*:*

Measures:

The parent interviews will include assessments for ADHD symptoms and diagnosis, co-morbidities, current treatments and satisfaction and cost associated with treatment, questionnaires about the child's health risk behaviors, quality of life, functioning and impairment, school performance, as well as questions about the parent's expectation about their child's future functioning, their parenting style, the parents' own mental health history and demographic information. The children will also be included in the annual assessments and will complete assessments for ADHD symptoms and diagnosis, co-morbidities, health risk behaviors, quality of life, functioning and impairment. The child's current teachers will complete surveys of ADHD symptoms, impairment, and about the child's school functioning. Assessment instruments are described in detail in Attachment B2.

Procedure:

Recruitment:

All participants of the interview phase of the PLAY study will be contacted and invited to participate in the follow-up assessments. The assessment schedule will include annual assessment visits, semi-annual surveys, and brief quarterly contacts. During the initial visits, parents will be asked consent to participate, consent for their child to participate, and consent for teachers to complete questionnaires. After parents consent for their children to participate, the children will be asked for their assent to participate. See Attachments D1-3 and E1-4.

All questionnaires are in English. For families where Spanish is the primary language, Spanish Consent forms will be available, and assessments will be conducted by bilingual English/Spanish interviewers, who are able to provide translations and explanations in Spanish if needed.

Assessment Schedule:

Teacher assessments: Teachers will be contacted between December and March to complete the rating scales. This has been determined in prior studies as the most optimal time period for teachers to complete surveys.

Annual visits: The annual assessments will involve an in-person interview, conducted at the assessment sites or at meeting rooms in local schools, at the convenience of the participants. All surveys and interviews will be administered during this visit. The selected modules from the DISC-IV interview will be administered via computer assisted interview. To limit the length of the assessment visit, parents will be mailed the self-report surveys to complete prior to the

assessment visit. However, interviewers will also provide assistance with completing the forms during the visit, as necessary.

For children under the age of 10, all assessments will be conducted via interview. For older children and teens, assessments may be conducted by self-report with an interviewer available for assistance and questions. Interviewers will ensure that children's responses will be kept confidential and not be reviewed by the parents.

Semi-annual assessments: Parents will be contacted by phone or mail to complete an updated contact information sheet, the treatment portion of the ADHD Treatment, Cost, and Client Satisfaction Questionnaire, and the Critical School Events form. Parents who need assistance with the surveys but cannot be interviewed by phone will be assessed in person.

The Strengths and Difficulties Questionnaire and the Vanderbilt Rating Scale will also be conducted again during the semi-annual assessment, if the annual assessment was conducted during the summer months, to ensure that the teacher and parent ratings on these two instruments are conducted no more than 3 months apart.

Quarterly contact: Parents will be contacted by phone or mail to verify contact information, to review any changes the treatment portion of the ADHD Treatment, Cost, and Client Satisfaction Questionnaire, and to assess recent school disciplinary actions. This information is gathered quarterly to maximize accuracy of recall.

Power:

Power calculations are based on the site with the more complicated study design (Oklahoma), which includes additional strata of school district. Because the final weights for the original PLAY study have yet to be determined, we present below power for un-weighted analyses, but do control for the anticipated impact of clustering at the school level. Three different intra-class correlations (ICCs) are inspected with that latter regard in mind. All models included 9 clusters (schools) of size 30, 8 of size 20, and 17 of size 10, with a 7:3 ratio of cases to controls which corresponds to expected final rates of the original PLAY study, based on data obtained to date.

We begin with linear growth models of a continuous outcome over the 5 assessments. Power estimates were modeled assuming an 85% retention rate across the duration of the study. Adopting the growth parameters of Muthén & Muthén (2002), we inspected two different growth effect sizes, .63 and .33, where effect size is defined as the difference in the mean slope across groups (cases and controls) divided by the slope standard deviation. These effect sizes corresponded to regression coefficients of .2 and .1 for the regression of the slope on a binary group indicator (with a 70:30% split representing the case status variable). We also modeled a background intercept difference between groups that accounted for 20% of the total intercept variation. All continuous outcomes maintained a residual variance of .5. The model predicts Cohen d effect sizes (mean difference divided by pooled standard deviation) at the last time-point of 0.26 (slightly larger than Cohen's (1988) small effect) and d = .52 (approximately equal to Cohen's medium sized effects) for the latent ES of .33 and .63, respectively. Each effect size was crossed with the three ICCs (.05, .10, and .20), and 500 Monte Carlo simulations were performed. Below is a table with the power and 95% CI coverage results for the slope difference regression parameter in this linear growth model.

Power and Coverage Performance for Group Slope Difference in Linear Growth Model

Power	Slope Effect Size	Coverage	Slope Effect Size

	0.63	0.33		0.63	0.33
ICC			ICC		
0.05	1.00	1.00	0.05	0.93	0.96
0.10	1.00	0.99	0.10	0.93	0.93
0.20	1.00	0.97	0.20	0.94	0.94

Power and coverage appear to be adequate for linear growth analyses of continuous outcomes.

The same analysis above for continuous variables might also be run for categorical outcomes. Such an analysis might be used, for example, to describe the change in positive predictive value of the original PLAY screen over time or to track the increasing rate of acquired comorbidities (e.g., health risk behaviors, sexual maturity milestones, etc.) in the high screen sample. Two such analyses were run below. The first attempts to detect gradual declines in the positive predictive value of the high screen sample over time. The analysis is meant to capture the effect of compensation, whereby, some high screen individuals learn to control their ADHD symptoms. The analysis begins with the preliminary positive predictive values of 0.56 and 0.02 for high and low screen groups respectively. Effect sizes of 0.05, 0.10, and 0.15 proportional change from assessment 1 to assessment 5 in the high risk sample versus no change in the low risk sample were assessed. Latent response Probit regression models were fit to translate latent continuous change into observed categorical outcomes. Two ICC values, at the latent intercept and slope levels, were inspected, 0.05 and 0.20. Again, 85% retention at each wave was assumed and modeled. Results are tabulated below.

Power and Coverage Performance for Compensation-Related Decline in Positive Predictive Value

Power	Change			Coverage	Change		
ICC	5%	10%	15%	ICC	5%	10%	15%
0.20	0.10	0.55	0.96	0.20	0.95	0.94	0.95
0.05	0.16	0.72	0.97	0.05	0.96	0.95	0.95

The simulations indicate acceptable power to detect declines from a baseline positive predictive value of 0.56 to 0.41 at year 6 assessment, even at the extreme ICC. The low power evidenced at 5 and 10% change is partly due to the large variability in the baseline estimate of positive predictive value (0.56). As shown below, power improves when considering change in high and low screen groups when baseline proportions move farther away from 0.50.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

In addition to investigators having a history of high levels of participation, all sites have plans for maximizing and increasing participation for both parents and youths. 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 an incentive schedule similar to the one proposed in this study (see section A9). The Oklahoma PI has had a previously funded project which was a large cohort of children (n = 288) with or at risk of having ADHD, who were predominantly from a poor inner city setting and where the project followed the children for 4 years maintaining a participation rate of 84% of the original sample. The measures that were collected from the

parents were similar to those proposed to be used in this study. Given this previous experience and proposed retention measures, we expect to achieve a response rate of 85%.

First, to increase participation, monetary incentives will be offered to the families who agree to participate. Please refer to section A9, **"**Explanation of Any Payment or Gift to Respondents" for level of incentives.

Second, frequent contacts with families will be made to ensure that contact is maintained with participants and to limit the extent of attrition. Instrument, scanning equipment, data management program, and statistical programs have been developed to streamline data collection and analysis. The process enables researchers to have a ready count of response rates and generate lists for further mailings to increase participation rates. A variety of tracking methods will be used to maintain contact with the PLAY cohort, keep addresses and contact information updated, and encourage continuing participation and include the following:

(1) Quarterly contact will be made with each family, reminding them of their participation in the study, indicating our desire to maintain contact, and asking again for verification of address and contact information. We will also ask for the name and contact information of two persons outside the immediate family who would know how to contact them. A random prize drawing will be used as an incentive for the parents to participate in the quarterly contact.

(2) Birthday greetings cards will be mailed each month to participants who have a birthday that month for every year of the study. The cards will be signed from the PLAY project to remind them of our continued interest in their growth and development. Each card will include a postage paid return envelop with a brief form to verify address, phone number, and guardian status. Participants will be informed that all returned forms will be placed in a drawing for a cash prize to be held that year.

(3) All mailings will be marked "address correction requested" to obtain forwarding addresses from the post office rather than having letters forwarded immediately to addressees. Though adding to the cost of mailing, address correction allows us to be notified of address changes on record with the postal service. This method is extremely helpful when participants are highly mobile.

(4) In our previous studies we have found that some of our participants have e-mail accounts. This no-cost correspondence has been helpful to the project for reminding participants of upcoming interviews, arranging interview times, or even rescheduling interviews. E-mail, of course, is not available to all participants. We will also use a toll-free number for the project so participants will be able to call in with address or phone number updates.

(5) Phone calls to the last listed phone number will be made to determine if the participant still has the same number or if a number change is provided for those who had moved recently.

(6) If mailings are not deliverable, and correct phone numbers unobtainable, PLAY team members will write or call the backup contacts who had been supplied by the parents to obtain a current participant address and phone number.

(7) Telephone directory searches (including city directories, telephone information services, and internet searches) will also be used to locate new phone numbers and addresses of participants.

(8) For those not located by other methods, reverse directories for the area will be used to locate neighbors of participants at the last known address. Neighbors will be asked if they have any

information about the family, including forwarding address and names of anyone who may know how to contact them.

(9) If participants are either unable or unwilling to attend in-person interviews, or move too far to travel to the assessment sites, they will still be able to participate in data collection. Parent data will be collected over the phone or by mail, and data on children older than 12 years of age will also be collected over the phone or by mail. The children will not be administered sensitive questions on the Health Risk Behavior Survey (i.e., drug use, sexuality) if not assessed in person, because confidentiality of answers cannot be ascertained.

(10) In cases where children's custody status changes, the new guardian/parent will be invited to participate in the study. In cases where children enter state custody, consent from the appropriate agency will be sought to maintain the child's participation in the study

If non-response becomes an issue, all sites will be generating and imposing statistical weights for non-response in additional to those generated for their sampling frame. These corrections will adjust the prevalence rates for biases due to non-response.

B.4. Test of Procedures or Methods to be Undertaken

The overall procedures and methods proposed in the current longitudinal study have been extensively tested in the initial PLAY study. For study procedures, sites utilized in person interviews, mail, and phone contact with participants which allowed them to determine the overall utility of the proposed procedures as well as to specify which survey instruments may be suitable for participants to complete as self-report (e.g., Health Risk Behavior Survey) and which instruments must be administered by phone or in-person interview (i.e., ADHD treatment, cost, and satisfaction questionnaire). Thus, the procedures have been tested with the same participants as will be invited for the longitudinal study.

The overall methods of the follow up study are also very similar to the methods used in the prior PLAY study. In addition to the data gathered for the collaborative study (i.e., health risks and ADHD symptoms and impairment), both studies conducted site specific assessments of quality of life, risk and protective factors utilizing either the same or similar assessment instruments as proposed in the current study. Specifically, all proposed instruments were used by at least one of the sites in either the PLAY study or in a study with similar populations, with the exception of the IPPA/PIML. However, that instrument is very similar in content and structure to an instrument that was utilized by South Carolina in a prior study.

Further, whenever specific items were added to the previously used survey (e. g., age appropriate items for the Health Risk Behavior Survey) they were selected from nationally administered surveys (e.g., YRBS, NSCH) or from studies with similar populations. See the Instrument Table in Attachment B1 for details. Thus, the methods and procedures largely have been tested and successfully implemented with the same participants as will be invited to participate.

B.5. Individuals Consulted on Statistical Aspects and Individuals and/or Analyzing Data

All of the following CDC and site investigators or representatives have been part of the process of considering the statistical issues and analysis potential of the proposed data collection. Additionally, these represent a wide variety of disciplines and expertise in analysis and study

design; most of the following individuals will be continuously involved in the analysis and reporting of the data collected in these studies.

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Additional information on site Key Site Staff

Oklahoma:
The principal investigator, Mark Wolraich, MD, has extensive experience in the study of ADHD in primary care settings and will direct all data collection efforts. The PI's primary research interest is the diagnosis and treatment of ADHD in primary care. He studied ADHD diagnosis and treatment practices among primary care physicians both through national surveys and direct screening and evaluation of patients in primary care physicians' offices (Wolraich, et al., 1990; Copeland, Wolraich, Lindgren, Milich & Woolson, 1987). He has also developed the teacher rating scale to be used as part of this study (and was utilized as the teacher screener in PLAY study), the Vanderbilt ADHD Teacher Rating Scale (Wolraich, Feurer, Hannah, Pinnock, & Baumgaertel, 1998), and has studying the educational/ medical interface in the diagnosis and treatment of ADHD in an urban setting using this instrument in previous studies (Wolraich, Hannah, Baumgaertel, Pinnock & Feurer, 1998; Wolraich, Hannah, Pinnock, Baumgaertel & Brown, 1996).

South Carolina:
Dr. Robert McKeown (epidemiologist) and Dr. Steven Cuffe (a board certified child psychiatrist) have worked on a longitudinal study of adolescent depression, suicidal behaviors, and other mental disorders since 1988 and 1992 respectively. In the initial stages, over 3400 7th and 8th students in a local school district were administered a screening questionnaire. Subsequently, 581 students and their parents selected in a stratified sampling design were assessed for psychiatric disorder and global function. In a second wave, as the students were finishing high school, the psychiatric assessments were repeated, with the addition of family history questionnaires and a new self-administered questionnaire. There were 490 of the original 581 in the follow-up, an 84% retention rate after an average of 6 years of follow-up. Dr. McKeown was responsible for the design and implementation of the tracing methods for the cohort. He and Dr. Cuffe have been involved in the publication of over 20 papers in peer reviewed journals, with several other papers now under review or close to submission. The joint findings from these studies are too extensive to be summarized here. However, there are a number of findings pertinent to this application.

Dr. Cuffe and Dr. McKeown have published on the epidemiology of ADHD in the community (Cuffe, McKeown, et al., 2001) and other aspects of child and adolescent mental health and service use (Cuffe et al., 1994; 1995; 1998; 2001). Their 2001 paper on Prevalence of Attention Deficit/Hyperactivity Disorder in a Community Sample of Older Adolescents was winner of the Elaine Schlosser Lewis Award for Research in Attention-Deficit Disorder, given by the American Academy of Child and Adolescent Psychiatry Award. The paper confirmed the need to re-examine the age-at-onset criterion for ADHD and suggested differential patterns of symptomatology and emergence of disorder in boys and girls. There were significant associations with comorbid affective disorders and with undesirable life events, perhaps related to the impact of disorder. Having fewer than both natural parents in the home and perception of family emotional cohesion were also associated.

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