ICR 0920-06BG: Response to OMB Desk officer Concerns/Questions (Conference call on July 11, 2007)

Item 1. Please clarify that the proposed sample is not representative of all youth with ADHD.

Response: That is correct. The text in Justification Section A2 (p.3-4) was edited to read to provide further clarification of this issue:

> *"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."*

Item 2. Please modify the incentive structure. Also, please explain how and when the incentives for the semi-annual phone/mailed interview will be distributed.

Response: The incentive structure was edited to be consistent across the 3 years of the study and consistent for children of all ages. 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 text and incentive Table in Justification Section A9 (p.9) were edited to read as follows:

> *"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."*

		Annual Incentive	
Participant	Annual In-person Interview	Semi-Annual Phone/Mail Interview	*Total*

Parent	$50	$25	***$75***
Child	$20	--	***$20***

Item 3. Please include the Diagnostic Interview Schedule for Children IV (DISC-IV) as a data collection instrument.

Response: The DISC-IV is now included as a data collection instrument and all relevant information on the DISC-IV has been included in the Justification text (including the revised burden table) and relevant attachments (B1 Instrument Table, B2 Instrument description, B36 DISC-IV Modules). The DISC-IV is a highly structured computer administered instrument with complicated skip patterns. The electronic versions of the questions (in pdf format) from the relevant modules of the DISC-IV are included in Attachment B36. The description of the instrument in Attachment B2 has been edited to provide more detail:

> "Attachment B36: *Diagnostic Interview Schedule for Children IV (DISC; Parent and Child Versions)*. Four out of 6 modules and the demographic section from the Diagnostic Interview Schedule for Children IV (DISC-IV) were selected for inclusion in this study in order to diagnose the following conditions: ADHD, Oppositional Defiant Disorder, Conduct Disorder, Generalized Anxiety Disorder, Major Depression/Dysthymia, Obsessive Compulsive Disorder, Post Traumatic Stress Disorder, Mania/Hypomania, and Tic Disorders. The DISC-IV is a highly structured diagnostic interview schedule developed by the National Institute of Mental Health. It is intended for use in research settings to provide a definitive diagnosis of psychiatric conditions such as ADHD as indicated by confirmation of the clinical features and diagnostic criteria for childhood disorders reported by parents up to age 17 and with additional reporting by children ages 8 and older. It is designed to assign a variety of psychiatric diagnoses in children according to criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV[4]), the most recent diagnostic criteria for mental disorders. Additionally, the DISC-IV gives a more complete symptom profile and a precise diagnostic picture of comorbidity than is possible with screening instruments or rating scales. In terms of the ADHD sub-module, it assesses symptom presence, impairment in multiple settings, and age of onset; all clinical features of ADHD required for diagnosis. The DISC-IV has been used widely in government research studies and in situations where ease of administration by non-clinical staff is important but a clinical diagnosis is desired. "

We also edited relevant sections regarding sensitive questions on the DISC in A11 (p.14). We have adjusted the Burden Table accordingly, reflecting the additional time burden of the Parent and Child version of the DISC-IV. Please note that while all parents will be administered the DISC-IV, only children ages 9+ will be administered this interview. The relevant section describing subsets of the sample in A12 (p.15) has been edited accordingly.

Section A12-1, Estimates of Annualized Burden Hours Table (p. 15-18):

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**

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.

Item 4. Please clarify when the child's assent will be conducted. Will children be asked for assent to participate only after their parent has been consented?

Response: Yes, the child will be asked for assent to participate only after their parent has been consented. In addition to relevant changes in the consent forms, the text in Justification Section B2 (p.2) was edited to read as follows:

> *"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."*

Item 5. Please verify the attrition rate utilized for the power calculations. Is it 85% at each assessment wave or 85% from the first to the last assessment wave of the study?

Response: The power was calculation on an estimated attrition rate of 85% throughout the entire study period. The following edits were made in Justification Sections B1 (p.1) and B2 (p.3), respectively:

"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."

"Power estimates were modeled assuming an 85% retention rate across the duration of the study."

Other issues.
In addition to the requested changes and modifications, with the inclusion of the DISC-IV we have made additional modifications to a few of the originally proposed data collection instruments in order to eliminate redundancy in data collection and reduce the time burden on participants. The following modifications were made:

- Deleting redundant questions from the Parent and Child Health Risk Behavior Surveys, the Parent Demographic Form, the Parent Critical Events forms, and the Parent Brief Impairment Scales.
- Deleting the Parent Pediatric Quality of Life scale (the child version is still used)
- Moving some questions off the Parent Questionnaire (Mental Health) and combining them with questions on the ADHD Treatment form.
- Reformatting the ADHD Treatment form (both the quarterly update and the first section of the ADHD Treatment, Cost, and Satisfaction Survey) for easier administration.

The modifications resulted in reduction of the burden for the following forms

- Parent and Child Health Risk Behavior Surveys
- Parent Critical Events forms

Edits were made in Justification Section A1-18 and relevant attachments, accordingly.

All documents which contain edits along with addition new documents (e.g., DISC-IV modules) have been included as part of this response.