Supporting Statement A for Request for Clearance:

Calibration of the Short Strengths and Difficulties Questionnaire (SDQ) in the National Health Interview Survey (NHIS)

OMB 0920-NEW

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November 18, 2010

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A. Justification

This new submission requests a two-year approval for the calibration of the Short Strengths and Difficulties Questionnaire (SDQ) for data collected through the National Health Interview Survey (NHIS), (OMB #0920-0214, expires 01/31/2012). Partial funding is through American Recovery and Reinvestment Act of 2009 (ARRA) (Public Law 111-5) funds.

1. Circumstances Making the Information Collection Necessary

The Short Strength and Difficulties Questionnaire (SDQ) is a five item mental health population-based screening questionnaire designed to assess the mental health of children aged 4 years and older. The SDQ has appeared intermittently on the National Health Interview Survey since 2005. It appears in 2005-2007, but was removed for 2008-2009 for budgetary reason, and returned in 2010.

However, the cutoff score that determines serious emotional disturbance (SED) has never been established. It is the purpose of the proposed study to calibrate the scores of the SDQ against diagnostic psychiatric interviews to establish the cutoff score that best determines SED. The proposed design is similar to the current successful method of using a cutoff on the screener in the NHIS Sample Adult file to signify adults with serious psychological distress, and to the calibration of the screener on the National Household Survey on Drug Use and Health (NSDUH) (OMB No. 0930-0110, expires 01/31/2012) to identify adults with serious mental illness.

Background: Statutory Mandates

The Center for Mental Health Services (CMHS) of the Substance Abuse and Mental Health Services Administration (SAMHSA) is congressionally mandated by the Public Health Service Act to provide descriptive information and policy analyses about the mental health service delivery system in the United States. Section 520 [42 USC 290bb-31] of the Public Health Service Act, establishes the Center for Mental Health Services (CMHS), of the Substance Abuse and Mental Health Services Administration (SAMHSA), and authorizes the Center to conduct surveys with respect to mental health. (See Attachment A2) Under the Public Health Service Act, the Secretary is required to shall collect data each year on the national incidence and prevalence of the various forms of mental illness and substance abuse. Relating specifically to mental health, the Administrator of SAMHSA, shall ensure that such activities include, at a minimum, the collection of data on—

- (1) the number and variety of public and nonprofit private treatment programs;
- (2) the number and demographic characteristics of individuals receiving treatment through such programs;
- (3) the type of care received by such individuals; and
- (4) such other data as may be appropriate.

Title II of Public Law (PL) 102-321, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act, established a federal block grant program for states to fund community mental health services for adults with "serious mental illness" (SMI) and children with a "serious emotional disturbance" (SED) (Center for Mental Health Services, 1993). (See Attachment A2) This law also requires the Center for Mental Health Services (CMHS) to develop operational definitions of SMI and SED and to create estimation methods based on these definitions (Center for Mental Health Services, 1993).

SAMHSA's mission also requires them to improve the availability, utility, and especially the quality of information. The Department of Health and Human Services has launched initiatives to improve the effectiveness, efficiency, and overall quality of health and health care through the development of standards for interoperable systems of clinical, public health, and personal health information. In addition to these requirements, the Institute of Medicine's 2006 report, Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series, called for implementing consumer-centered approaches to enhance consumer and family decisionmaking, increase coordination of care between specialty and medical sectors, strengthen the evidence-based and quality infrastructure, and improve workforce development. All of these benefits rely on improvements in information systems maintained by State mental health and substance abuse authorities and service providers in the public and private sectors. Accordingly, there is a need for SAMHSA to exercise leadership in this area—to ensure sufficient attention to these issues in the development of national data standards and electronic health records (EHRs), and to assist States and providers in adapting to the emerging healthcare information environment.

Child Mental Health and the NHIS

To fulfill this mandate, CMHS needs to obtain reliable population estimates of children and adolescents with SED as well as information about their characteristics, services use, medical co-morbidities, insurance status, and other information critical to decision making. To date, there are no national estimates of the number of children and adolescents with SED.

The NHIS (OMB #0920-0214, expires 01/31/2012) represents the only possible national survey platform to serve as the basis to establish a prevalence estimate of SED among both children and adolescents. The NHIS is conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC) to comply with the NCHS mandate under 42 USC 242k (See Attachment A1) to collect, on an annual basis, statistically valid data on the amount, distribution, and effects of illness and disability in the population and on the utilization of health care services for such conditions. NHIS data are used widely throughout the Department of Health and Human Services (DHHS) to monitor trends in illness and disability and to track progress toward achieving many of the Year 2010 Health Objectives for the Nation. The data are also used by the public health research community for epidemiologic and policy analysis of such timely issues as characterizing those with various health problems, determining barriers to accessing and using appropriate health care, and evaluating the impact of changes in federal health programs.

Past efforts to collect additional data about children's mental health in the NHIS have included the use of an abbreviated form of the Child Behavior Checklist (CBCL) in 1988 and

1997–2000 and general questions on developmental delay in the 1988 NHIS Child Health Supplement. The 1994–95 NHIS Disability Survey also included useful questions on functional developmental delay for infants and young children. However, for school-aged children, the abbreviated forms of the CBCL lacked validation studies and the general developmental delay questions were too broad to ascertain the state of children's current mental health.

Since 2001, both CMHS and the National Institute of Mental Health have provided support for a mental health component on the NHIS. This decision was made in recognition that the NHIS is the primary source of much of the information required about a broad range of health problems, including mental health, faced by people living in households, their access to health care or disparities that may exist in the delivery of healthcare. Information from the NHIS continues to be used to establish progress toward national mental health objectives and well-being indicators. Further, no other national household survey has the capacity to produce estimates of the prevalence of mental health problems for children younger than 12.

The use of mental health screening scales such as the SDQ on household surveys such as the NHIS provides a practical approach to gathering information on the number and characteristics of children with mental health problems. Although detailed structured psychiatric interviews remain the most accurate measures for estimating prevalence, they impose significant administrative and respondent burden which deem them impractical for ongoing usage in federal household surveys. An alternative approach is to use screening scales such as the SDQ which have a high degree of concordance with more extensive instruments that can identify mental health problems.

The Strengths and Difficulties Questionnaire

On December 6, 2006 CMHS convened a panel of child and adolescent mental health experts to help them address their charge to develop a reliable way to produce estimates of children with SED. The panel recommended that CMHS continue to collect mental health information about children and adolescents using the NHIS. In addition, the experts recommended the continued use of the short SDQ for the screening of mental health problems. However, the mental expert panel noted the lack of a reliable cutoff score and proposed calibrating the short SDQ to a standard psychiatric measure.

The mental health epidemiologists agreed that the appropriate gold standard for the calibration of the short SDQ was the Child and Adolescent Psychiatric Assessment (CAPA) (a standard clinical interview for children aged 9-17 years) or the Pre-School Age Psychiatric Assessment (PAPA) (a standard clinical interview derived from the CAPA for children aged 4- 8 years. For the purposes of the proposed study, the CAPA and the PAPA are the only instruments designed to assess children in a wider age range, those aged 4-17 years. (The NCHS ERB has since determined that children aged 12-17 years will be interviewed and not those aged 9-11 years.) Structured or semi-structured mental health interviews, such as the CAPA and PAPA, provide highly reliable and valid diagnoses outside a medical treatment setting. These interviews, conducted by clinicians or trained laypeople, are often used for detailed epidemiological surveys, and can be used reliably to calibrate a short screener such as the SDQ.

Privacy Impact Assessment

A Privacy Impact Assessment was submitted and on July 13, 2010 the National Health Interview Survey received its Authority to Operate, expiring, July 13, 2013.

Overview of Data Collection System

Approximately 800 cases drawn from children aged 4-17 years will be assigned to four strata defined by percentiles of the total difficulties score from the SDQ: (1) >= 90th percentile, (2) 75th to < 90th percentile, (3) 50th to < 75th percentile, (4) <50th percentile. The sample will be equally distributed across these strata.

The NHIS Computer Assisted Personal Interview (CAPI) instrument will be programmed to select the sampled respondents. The Census Bureau will deliver the names and telephone numbers for households identified for follow-up to NCHS and NCHS will provide this information to the contractor (Research Triangle Institute (RTI) International) through secure means. Because potential respondents for the follow-up are drawn from respondents to a personal visit survey, most of the addresses are expected to be accurate.

For the households selected to participate in the calibration study, an advance letter (Attachment H) will be sent to the parents who answered questions about their children in the National Health Interview Survey. Included in the advance letter will be a $5 incentive for the parents. In addition, the parent and child will each be promised $25 at the completion of the interview. Parents will receive $25.00 in cash and children will receive a $25 gift card.

Interviewers will contact the household by telephone, and obtain the proper permissions, consents and assents from participants before commencing the clinical interviews. All parents will be administered either the PAPA (see Attachment C) or the Parent CAPA (see Attachment D) , depending on the child's age. They will also be administered the short SDQ. Children aged 12- 17 years will be administered the Child CAPA (see Attachment E).

Duke's Center for Developmental Epidemiology (CDE) will lead the 5-day in-person training program and certification of the CAPA and PAPA with RTI's assistance. RTI and Duke will work together to develop clinical interviewer manuals and training materials. The trainer contracted to do the CAPA and PAPA training is an employee of Duke University who has conducted all similar trainings for Duke's previous studies using these interview protocols. Duke researchers have conducted multiple epidemiological studies using the CAPA and PAPA protocols which total several thousand interviews conducted over the past decade. These studies have employed interviewers with parallel expertise to that required in this study and who were recruited in a manner consistent with current study plans. Training on telephone interviewing techniques and procedures will be led by RTI drawing from their corporate experience conducting telephone interviews with children, adolescents and their families.

The interviews are coded by the interviewers directly following the interview. A Duke University programmer will apply to the interviewer data a Duke-developed diagnostic algorithm designed to generate DSM_IV diagnosis representing Serious Emotional Disturbance (SED) to produce a full SAS dataset to be delivered to RTI. The symptom information gathered using the CAPA and PAPA is being used to determine whether or not each child meets the criteria for one or more of five DSM-IV diagnoses: depression, anxiety, attention deficit disorder, oppositional defiance disorder, and conduct disorder. In the cases where the scores meet the diagnostic criteria as set forth by the DSM-IV, the results will be reported to the parents

(see the advance letters and consent scripts in Attachment H). An RTI statistician will conduct the calibration analysis and determine the cutoff score to be used in the NHIS. A recode will be placed on the 2010 NHIS microdata file signaling children likely to have SED as determined by their SDQ score.

NCHS staff will monitor all aspects of the calibration.

Items of Information to be Collected

Items (in columns, page numbers within attachment are shown)	Attachment C Parent interview for children aged 4-8 years (PAPA)	Attachment D Parent interview for children aged 9-17 years (P-CAPA)	Attachment E Interview for children aged 12-17 years (C-CAPA)
• Blank pages	C3 – C16	D4 – D17	E2 – E15
• Moods and Feelings	NA	NA	E18 – E20
• School/Work Performance and Behavior/Daycare	C17 – C30	D23 – D47	E21 – E32
• School/Separation Anxiety	C193 – C207	NA	E33 – E46
• Worries	C229 – C232	D48 – D50	E47 – E50
• Anxious Affect/Hypomania and Mania	Anxiety C233-C252 Hypomania C79 – C96	Anxiety D52 – D67	Anxiety E51 – E67
• Depression	C45 – C78	D68 – D99	E68 – E97
• Food Related Behavior	C169 – C188	D100 – D101	E98 – E99
• Sleep Problems	C208 – C228	D102 – D105	E100 – E103
• Oppositional/Conduct Disorder	C115 – C168	D122 – D158	E104 – E143
• Play and Peer Relationships	C31 – C44	NA	NA
• Incapacity Ratings	C253 – C299	D160 – 217	E145 – E203
• Somatization	C189 – C192	D18 - D22	NA
• Attention Deficit and Hyperactivity Disorder	C97 – C114	D106 – D121	NA
• Child and Adolescent Impact Assessment	C300 – C315	D218 – D233	NA

Information in identifiable form (IIF)

This study does not collect information in identifiable form. However, respondent name, address and telephone number were obtained, with consent, from the NHIS data file.

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

There is no website for this project.

2. Purpose and Use of Information Collection

Data collected in the calibration study will be used to create an algorithm that will determine the appropriate cut-off score on the short SDQ that indicates serious emotional disturbance. The calibration model developed from this analysis will then be applied to the full sample for estimating SED which will allow for the production of recodes on the NHIS that flag children with SED. This will allow for national estimates of children with SED

Privacy Impact Assessment Information

A Privacy Impact Assessment was submitted and on July 13, 2010 the National Health Interview Survey received its Authority to Operate, expiring, July 13, 2013.

NCHS data are collected under an Assurance of Confidentiality. Only those NCHS employees, specially designated agents, including the U.S. Census Bureau, and our full research partners, in this case, RTI, who must use the personal information for a specific purpose can use such data. Everyone else who uses NHIS data can do so only after all identifiable information is removed.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. All NCHS employees as well as all contract staff, in this case, RTI, receive appropriate training and sign a "Nondisclosure Statement." Staffs of collaborating agencies are also required to sign this statement and outside agencies are required to enter into a more formal agreement with NCHS. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access. See A10 for more details.

3. Use of Improved Information Technology and Burden Reduction

This is a one-time study. Burden has been contained by keeping the length of the questionnaires to about 60 minutes for adults and to 45 minutes for children and by keeping the sample size small. No more than 1200 persons are expected to be interviewed.

The interviews will be conducted by Computer Assisted Personal Interview (CAPI), using Tablet PCS, which reduces the time required for collecting, transferring data, processing data, and releasing data. CAPI usually reduces the average duration of interviews, compared to a paper questionnaire with identical content.

There are no technical or legal obstacles to burden reduction.

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

The panel of child and adolescent mental health experts that convened on December 6, 2005 indicated the necessity for this calibration study because it had not yet been done for the short SDQ as a measure of Serious Emotional Disturbance in the NHIS.

There are no similar data available.

5. Impact on Small Businesses or Other Small Entities.

This information collection does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time study that is not expected to be repeated.

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

None. This request complies fully with 5 CFR 1320.5.

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

A. Public Comment

In compliance with 5 CFR 1320.8(d), an agency 60-day notice soliciting comments on this data collection was published in the Federal Register on May 26, 2010 (Vol. 75, No. 101, pages 29552-29553) (Attachment B). No comments were received.

B. Other consultations outside the agency

On December 6, 2006 a panel of child and adolescent mental health experts recommended that CMHS continue to collect mental health information about children and adolescents through the NHIS. In addition, the experts recommended the continued use of the short SDQ for the screening of mental health problems in children. They also recommended that the short SDQ be calibrated in the NHIS.

In addition, the following persons have regularly been consulted on the design of this study.

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9. Explanation of any Payment or Gift to Respondents

The sponsor of this project, SAMHSA, conducted an incentive experiment for the National Survey of Drug Use and Health (NSDUH) (OMB NO. 0930-0110), a survey that contains substantial mental health sections. A randomized, split-sample, experimental design was included with the main study data collection to compare the impact of $20 and $40 incentive treatments to a $0 control group on measures of respondent cooperation, data quality survey costs, and substance abuse prevalence estimates. Overall, the study found that the use of monetary incentives significantly increases response rates. Specifically it showed substantial gains in cooperation with when a $20 incentive versus no incentive was offered (78.8% vs. 69. 2%), with more modest gains when a $40 vs $20 incentive was used (78.8 vs. 83.3).

The findings were especially striking among 12-17 years olds where a $20 incentive shifted the cooperation rates from 78.8 to 91.1%, with the $40 incentive bumping the cooperation rate to 95.1%. Teenagers are an integral part of the proposed survey because only they, not their parents can give accurate information about symptoms that help to determine whether or not the teenager is experiencing such internalizing disorders as depression and anxiety.

Other research that indicates that prepaid and promised tokens of appreciation may have an impact on increasing response rates to telephone surveys (Cantor, O'Hare, and O'Connor, 2008).

For this study, we propose to include a $5 dollars prepaid incentive with the advance letter that promises an additional $25 once the interview is implemented in whole or in part. We think the combination of these two incentives will maximize cooperation rates without incurring significant survey costs.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of individuals participating in the calibration is protected by section 308(d) of the Public Health Service Act (42 USC 242m), which states:

> "No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (PL-107-347), which states:

> "Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

<u>Privacy Impact Assessment Information</u>

A. The Privacy Act of 1974 (5 U.S.C. 552a) "requires the safeguarding of individuals", and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a Federal agency according to either individual's name or some other identifier. This law also requires that such records in NCHS are to be protected from "uses other than those purposes for which they were collected."

   The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have reviewed this package and have determined that the Privacy Act is applicable.

   This study is covered under Privacy Act System of Records Notice 09-20-0164 ("Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population").

B. It is the responsibility of NCHS employees, including NCHS contract staff, to protect and preserve all data from unauthorized persons and uses. All NCHS employees as well

as all contract staff have received appropriate training and made a commitment to assure confidentiality and have signed a "Nondisclosure Affidavit". It is understood that protection of the confidentiality of records is a vital and essential element of the operation of NCHS, and that Federal law demands that NCHS provide full protection at all times of the confidential data in its custody. Only authorized personnel are allowed access to confidential records and only when their work requires it. When confidential materials are moved between locations, records are maintained to insure that there is no loss in transit and when confidential information is not in use, it is stored in secure conditions.

NCHS policy requires physical protection of records in the field, and has delineated these requirements for the data collection contractor. The contractor also has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees must sign. The contractor provides all safeguards mandated by Privacy Act and Confidentiality legislation to protect the confidentiality of the data. The contractor's data security procedures comply fully with security requirements delineated by the Information Resources Management Office of CDC.

It is NCHS policy to make data available via public use data files to the scientific community. Confidential data will never be released to the public. For example, all personal information that could be potentially identifiable (including participant name, address, survey location number, sample person number), are removed from the public release files. The NCHS Disclosure Review Board reviews all files that will be released, to assure that directly or indirectly identifiable data are not included.

C. A copy of the consent script is shown in Attachment H.

D. Respondents are advised of the voluntary nature of the data collection in the advance letter and consent script (Attachment H).

11. Questions of a Sensitive Nature

The proposed study has received approval from the NCHS Ethics Review Board which has determined that the questions and the protocol pose no more than minimal risk (Attachment G).

The questions determine symptoms that are associated with five common psychiatric disorders in children: depression, anxiety, attention deficit disorder, oppositional defiance disorder, and conduct disorder. The questions are those used in routine psychiatric examinations of children.

12. Estimates of Annualized Burden Hours and Costs

The mean interview time for parents is expected to be no more than 60 minutes and mean interview time for children is expected to be no more than 45 minutes. In addition the Short Strength and Difficulties Questionnaire, which was asked of parents in the original NHIS, will be fielded again. That will take an additional 1 minute per respondent. It is anticipated that approximately 800 parents will be selected into the study (401 over the annualized two-year

request) and 600 children and adolescents aged 12-17 years (300 on an annualized basis). Younger children will not be interviewed. The total average annual burden is 633 hours.

Estimated Annualized Burden Hours

Type of Respondent	Type of Form	Number of Respondents	Number of Responses per Respondent	Average burden per Response in hours	Total Burden in Hours
Parents of children aged 4-8 years	Pre-school Age Psychiatric Assessment (PAPA) (Attachment C)	63	1	1	63
Parents of children aged 9-17 years	Child and Adolescent Psychiatric Assessment: Parent Version (CAPA) (Attachment D)	338	1	1	338
Children, aged 12-17	Child and Adolescent Psychiatric Assessment: Child Version (CAPA) (Attachment E)	300	1	45/60	225
Parents	Short Strengths and Difficulties Questionnaire (SDQ) (Attachment F)	401	1	1/60	7
Total		701			633

B. Cost to Respondents

At an average wage rate of $20 per hour and an average length of interview of 52 minutes, the average cost per respondent is about $17.33. (Wage data are from the most recent National Compensation Survey and can be found at the Bureau of Labor Statistics: http://www.bls.gov/ncs/ocs/sp/nctb0298.pdf). This estimated cost does not represent an out of pocket expense, but represents a monetary value attributed to the time spent doing the interview. It is more than offset by the incentive offered to the respondent.

Estimated Annualized Respondent Costs

Total Burden Hours	Respondent Wage Rate per Hour	Total Respondent Costs
633	$20.00	$12,660

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

None

14. Annualized Cost to the Government

The Annualized cost to the government based on FY 2010 figures is:

CONTRACT	$686,149
NCHS Staff	$ 50,000
TOTAL	$736,149

These contract costs include data collection including hiring, training and supervising the interviewers; and data processing, editing, and documentation of the data file. It also includes calibrating the short SDQ and writing analytic and methodological reports.

15. Changes in Hour Burden

This is a new data collection.

16. Time Schedule, Publication, and Analysis Plans

Deliverables and Activities	Target Dates
• ERB Clearance	May, 2010
• Data Collection Kick0ff meeting	October, 2010,
• OMB Clearance	March, 2011
• Verification of confidentiality procedures (including systems security) and nondisclosure	

affidavits signed	January, 2011
• Deliver eCAPA and ePAPA instruments	April, 2011
• Data collection begins	May 2011
• Data collection ends	February, 2012
• Calibration report finalized	June 2012
• Data tape and documentation delivered	July 2012
• Final report	July 2012

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

N/A

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

None

Reference:

Cantor, D, O'Hare, BC and KS O'Connor. 2008. The Use of Monetary Incentive to Reduce Nonresponse in Random Digit Dial Telephone Surveys. Pp. 471-498 Lepkowski, JM, C Tucker, JM Brick, E deLeeuw, L Japec, PJ Lavrakas, MW Link and RL Sangster (eds.) *Advances in Telephone Survey Methodology*.