

## **INFORMATION COLLECTION REQUEST**

Testing and Development of Materials Promoting Prevention and Control of Traumatic  
Brain Injury in Schools

Supporting Statement A

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- Attachment 1: Authorizing Legislation, Section 301 of Public Health Service Act 42 U.S.C. 242k**
- Attachment 2: Screener Instrument for Nurses, Counselors, Psychologists, and Administrators**
- Attachment 3: Moderator’s Guide for In-Depth Interview for Nurses, Counselors, and Psychologists**
- Attachment 4: Moderator’s Guide for In-Depth Interview for Administrators**
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## **Supporting Statement for Pretesting Traumatic Brain Injury Materials for School Professionals**

### **A. Justification**

#### **A.1 Circumstances Making the Collection of Information Necessary**

##### Background

The Centers for Disease Control and Prevention (CDC) requests a **new** information collection request for a study entitled, “Pretesting Traumatic Brain Injury Materials for School Professionals.”

Each year, an estimated 1.4 million Americans sustain a traumatic brain injury (TBI). A TBI is caused by a blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain.

Children ages 0 to 4 years and adolescents ages 15-19 are at the greatest risk of sustaining a TBI, as they often sustain TBIs from a host of mechanisms including falls (down stairs or from heights such as counter tops or beds), direct impacts (e.g., getting hit in the head with a ball), and motor vehicle crashes.

In order to address this important public health problem among young children and adolescents, CDC plans to conduct a national TBI educational initiative aimed at school nurses, school counselors, school psychologists, and school administrators. As part of the initiative, CDC will develop educational materials and messages for these audiences, as well as tools for partners, to help improve the prevention, recognition, and management of TBI among school-aged children and adolescents.

School nurses, school counselors, school psychologists, and school administrators are important audiences for this initiative, as they are well positioned to address short- and long-term issues related to TBI. These audiences play an important role in addressing the needs of students and working collaboratively with educators and parents. School nurses need current, reliable, and easy to use materials about TBI, to keep them up-to-date on the issue and assist them in educating and caring for students who come to them with a suspected TBI. Nurses, counselors, psychologists, and administrators can promote prevention of TBI in the school setting and inform educators and parents about TBI prevention and recognition in the classroom, on the playground and on the field. They can also work with schools to institute TBI specific back-to-school and return-to-play plans.

This new Information Collection Request (ICR) is being submitted under Section 301 of the Public Health Service Act (42 U.S.C.241) authorized on December 31, 2004, and copied into Attachment 1.

## Privacy Impact Assessment

The CDC Privacy Act Officer determined that the Privacy Act is not applicable on October 6, 2008. Although personal information (e.g., name, business mailing address, business email address, phone number for interview) will be gathered by a professional recruitment vendor during in-depth interview recruitment, no personal identifiers (e.g., home address or phone number, social security number, etc.) will be collected or maintained.

## Overview of the Data Collection System

The information collection (IC) will consist of 45, 60-minute in-depth interviews. Data will be collected and analyzed by the Academy for Educational Development (AED), a contractor for this task based in Washington, D.C.

Formative research, including up to 45 interviews, will be conducted with school nurses, school counselors, school psychologists, and school administrators. Interview participants must currently be employed at an educational institution. Upon analysis of qualitative interview data, educational materials will be developed and/or revised.

Interviewees will be screened and selected by a yet to-be-determined professional market research firm (see Attachment 2 for Screener). Potential participants will be identified from the research firm's database. Interview participants will be school health professionals (school nurses, counselors, or psychologists) and school administrators (including superintendents, principals, and vice-principals). Participants will be recruited from diverse geographic areas across the United States. In recruiting participants, we hope to satisfy the following criteria:

- A mix of levels of health professionals (e.g., licensed practical nurses, nurse practitioners, master's- and doctorate-level counselors, etc.)
- A mix of school grade levels (elementary, middle, and high school) and school types (public and private)
- A mix of school geographic settings, including rural, suburban, and urban (including inner-city)
- A mix of number of schools covered by health professionals (e.g., only work in one school or work in several schools)
- At least five school nurses who have had a student with a TBI

The interviews will be conducted by trained researchers and will use a semi-structured interview instrument (see Attachments 3 and 4 for the Interviewer Moderators' Guides). Objectives of the interviews will include:

- Explore the ways in which school health professionals and administrators view traumatic brain injury and health education materials related to TBI.
- Test educational materials for school health professionals to distribute to students, parents, and staff.

Interviews will be audio recorded and transcribed. All transcripts from the in-depth interviews will be reviewed through thematic analysis. This will enable the researchers to look for commonalities and distinctions between the groups of interest, which will help synthesize ideas for concepts, messages, products, and services.

AED will provide CDC with aggregate demographic data on participants but will not deliver to HHS/CDC or others any personal identifiers of participants. No demographic data or combination of data elements that would lead to the identification of an individual will be provided. AED will develop and submit a report in an agreed-upon format summarizing the responses provided by participants. If appropriate, transcripts of conversations without personally identifiable information will also be forwarded to CDC.

In following standard guidelines for security of data, the contractor will keep all records containing sensitive information (e.g., audio recordings of interviews, transcripts, etc.) in secured file cabinets and password protected electronic folders when not in use. Audio recordings and backups will be destroyed upon completion of reports. Transcripts will be held for three years in secured areas, after which they will be destroyed.

#### Items of Information to be Collected via In-Depth Interviews

The goal of these interviews with school professionals is to understand what school professionals (including school nurses, school counselors, school psychologists, and school administrators) think about materials related to TBI. The materials will provide guidance on how to prevent and recognize TBI in students. The content discussed in these interviews will be used to refine materials and develop future materials.

A professional recruitment vendor will collect information in identifiable form (IFF). This information will collected consists of:

- Participant Name
- Mailing Address
- Phone Number
- Email Address

AED will receive participant first names, mailing addresses, phone numbers, and email addresses. Neither AED nor the recruitment vendor will share this personal information with CDC.

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

The telephone interviews will not involve any websites or website content directed at children under the age of 13.

## **A.2. Purpose and Use of Information Collection**

Formative research is critical to developing messages and materials that are both effective at communicating their message and invoking the desired audience response and doing so for the least cost to the government.

The formative evaluation process is used to determine whether a draft message or program concept is effective in reaching and communicating with its audience. Pretesting involves presentation of draft messages, materials, and program concepts designed to convey specific information to a sample of the audience for whom the strategies are intended. These respondents are asked to give their reaction to the messages through either individual or group interviews. Messages, materials, and program concepts are assessed for these qualities:

- Attention - Do the concepts attract and/or hold the audience's attention? For example, if they were given this fact sheet by a supervisor, would they read it?
- Comprehension - Are the messages or main points clearly understood? Does the main theme of the message get across to the audience? Is the language clear? For example, a respondent may be asked whether a fact sheet clearly explains ways to recognize TBI.
- Personal Relevance and Self-efficacy - Do members of the target audience perceive the message as personally relevant? For example, do school counselors believe the content on the materials relates to their work responsibilities?
- Accessibility - Will the message reach the target audience? For example, will school administrators disseminate materials to school nurses, counselors, and psychologists?
- Usability - How likely is the respondent to use the information in the format provided? For example, is the content presented in a well-organized, logical, and user-friendly way?

Respondents' input and reactions to each of these areas provide insight into how the audiences for these messages and activities may react and how the concepts should be formulated, revised, or disseminated to communicate most effectively.

Other information gathered on respondents such as gender, age, race/ethnicity, and geographic location provides a basis for evaluating whether the messages may be perceived differently by different segments of the audience. For example, rural school professionals may find a particular message on recognizing TBI more relevant than professionals from suburban or urban environments.

Data obtained from concept and message testing will inform CDC of critical elements (content, pictures, images, etc.) to include and/or omit from current and future messages and materials concerning TBI. Additionally, data collected from school administrators will indicate whether this audience would disseminate these materials to school nurses, counselors, psychologists, and parents.

The results of the concept testing will be shared with other government agencies, state and local health departments, and other partners.

Without clearance to conduct formative research with members from priority audiences, CDC will not be adequately prepared to communicate effectively to these groups about primary and secondary prevention of TBIs.

#### Privacy Impact Assessment Information

Personal information (e.g., name, business mailing address, business email address, phone number for interview) will be gathered during in-depth interview recruitment. Recruitment will be conducted by a professional recruitment vendor. Name, business mailing address, and business email address will be collected so AED can mail (both physically and electronically) a package of materials to participants for use during the interview. A phone number where participants can be reached for the interview is necessary so AED's professional interviewers can contact participants. This information will be destroyed upon completion of interviews.

Personal identifiers (e.g., home address or phone number, social security number, etc.) will not be collected or maintained.

The proposed data collection will have little or no effect on the respondent's privacy.

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

The type of information necessary for this research requires interviews. Telephone interviews will be used to address the geographic diversity of the U.S. population since face-to-face interviewing is not necessary to accomplish the research objectives. Potential participants will be contacted using telephone or e-mail.

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

A review of the literature and on-line research was conducted, and informal expert phone calls were made to the National School Nurses Association, National American School Counselors Association, and National Association of School Psychologists to identify any existing materials and assess what is already known about developing messages to raise awareness about the prevention and recognition of TBI among school professionals and parents. The information uncovered focused on transitioning TBI patients back to schools as opposed to preventing and controlling TBI in schools. Additionally, the experts consulted shared that there is a lack of TBI knowledge among school nurses and that school counselors and psychologists do a fair amount of work with students affected by TBIs. This proposed project would be integral in increasing the understanding of prevention and control of TBI in schools among school professionals and parents.



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

No small businesses or entities such as community-based organizations or health care providers will be involved in this data collection.

#### **A.6. Consequences of Collecting the Information Less Frequently.**

This is a single data collection, not an ongoing activity. Respondents will not be re-contacted. Because no testing has been done of messages and materials directed at school professionals about preventing and recognizing TBI, this project fills the gap in the knowledge needed to jumpstart approaches that can reduce TBI.

Inability to conduct this study will prevent CDC from capitalizing on an important opportunity to produce effective messages to raise school professionals' and parents' awareness of TBI.

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

This request fully complies with the guidelines of 5 CFR 1320.5.

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

A. The 60-Day Federal Register Notice (FRN) was published in the *Federal Register* on October 16, 2008, Vol. 73, No. 201, Pages 61424-61425 (see Attachment 5 for the *Federal Register* notice). There were no public comments received.

B. CDC's National Center for Injury Prevention and Control continually coordinates with other U.S. government agencies on projects related to TBI. CDC consults regularly with other agencies, to help ensure accuracy and consistency, and to avoid duplication of effort. CDC also regularly consults and coordinates with non-U.S. government organizations through formal and informal channels. Table A.8.B shows the individuals consulted related to this information collection. CDC did not observe duplications of efforts.

**Table A.8.B. Individuals Consulted**

Year of Consultation	Name	Title	Email Address	Phone Number
2008	Jill Cook	Assistant Director American School Counselor Association	<a href="mailto:jcook@schoolcounselor.org">jcook@schoolcounselor.org</a>	(703) 683-2722
2008	Janet Tyler, Ph.D.	Director Neurologic Disabilities Support Project/ Kansas Instructional Support Network	<a href="mailto:jtyler@kumc.edu">jtyler@kumc.edu</a>	(913) 588-5947
2008	Ron Savage	Vice President of Lash & Associates Publishing/Training Inc.	<a href="mailto:rksavage@comcast.net">rksavage@comcast.net</a>	(856) 816-0427
2008	Marian Smithey, RN, BSN, MS, NCSN	Nursing Education Director National Association of School Nurses	<a href="mailto:msmithey@nasn.org">msmithey@nasn.org</a>	(240) 247-1616
2008	Heather Crown	Outreach and Technical Assistance Field Specialist TBI Technical Assistance Center National Association of State Head Injury Administrators	<a href="mailto:hacrown@tbitac.nashia.org">hacrown@tbitac.nashia.org</a>	301-656-3150

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

It is standard practice in commercial market research to offer recruited respondents some form of remuneration for the time they spend engaged in a pretest activity. Small amounts of money, a free meal or snack scheduled around the time of the pretest, and/or remuneration for parking and/or transportation are most often used.

The majority of the respondents for the research will consist of individuals and representatives of institutions that frequently do not place high priority on prevention of TBI. Therefore, responding to the interviews will be outside the scope of work for many participants. For this reason, a small token of appreciation will be offered to all potential participants, in the form of a one-time payment of \$40.00.

There is extensive literature to support the use of incentives, primarily monetary incentives, as a supplement or complement to other efforts of persuasion to ensure recruitment of a representative sample, especially among hard-to-reach and minority populations.<sup>1,2</sup> In studies for both commercial market research and social sciences, findings indicate that respondents who receive these tokens of appreciation provide valid input, and their inclusion makes for a more representative sample.

#### **A.10. Assurance of Confidentiality Provided to Respondents**

No assurance of confidentiality will be provided to respondents. However, CDC and its contractor, AED, will follow best practices to minimize collection of identifying information, and to keep data securely stored. Participants will be informed that the information they provide will be kept private to the extent permitted by law.

This research has been approved for exemption from 45 CFR 46 by AED's Research Integrity Officer on the grounds that the protocol poses no risk to participants, nor does it involve collection of personal records. Individuals recruited for the interviews will not be from vulnerable groups such as children, incapacitated or incarcerated people who are unable to understand their rights to refuse to participate or to discontinue the interview at any time (see IRB Exemption Review attached as Attachment 6).

#### Privacy Impact Assessment Information

A. The CDC Privacy Act Officer has determined that the Privacy Act is not applicable. Although personal information (e.g., name, business mailing address, business email address, phone number for interview) will be gathered during in-depth interview recruitment, no personal identifiers (e.g., home address or phone number, social security number, etc.) will be collected or maintained.

B. CDC's contractor, AED, adheres to conventions for ensuring data security (see Attachment 7, AED Data Security Policy). These practices include minimizing research staff who have access to the information, keeping identifying information in locked file cabinets and password protected electronic folders, and destroying identifying information at the earliest opportunity consistent with the research. Audio recordings and backups will be destroyed upon completion of reports. Transcripts will be held for three years before being destroyed.

C. After completing the participant screener (see Attachment 2 for Screener with verbal consent information) and qualifying for the study by telephone, participants will be read

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<sup>1</sup> Singer E and Kulka RA. Paying respondents for survey participation. In Ver Ploeg M, Moffitt RA, Citro CF (eds). Studies of Welfare Populations: Data collection and Research Issues. National Academy Press: Washington, DC 2001. Available at <http://www.nap.edu/openbook/0309076234/html>. Accessed on May 13, 2008.

<sup>2</sup> Kovac MD, Markesich J. Tiered incentive payments: getting the most bang for your buck. Presentation at the Annual Conference of the American Association for Public Research, 2002.

informed consent information and asked to provide verbal consent. The informed consent information explains the nature of the questions and their uses, and specifies that respondents do not have to respond to any question that makes them uncomfortable. Informed consent information will be reread to participants at the beginning of the interview (see Attachments 3 and 4 for the Interview Moderators' Guides).

D. Respondents will be informed that the information they share is voluntary and will be kept private to the extent permitted by law. Personal information, such as age and income, will not be collected for this research.

### **A.11 Justification for Sensitive Questions**

There are no sensitive questions in the interviewers' guides.

### **A.12. Estimates of Annualized Burden Hours and Costs**

A. Table A.12.A presents burden hour estimates for this data collection. These estimates encompass data collection in 30 in-depth phone interviews with school nurses, counselors, psychologists and school administrators, as well as 15 in-depth interviews with school administrators. Each recruiting phone call (with use of the screener) for the phone interviews is expected to last ten minutes. Each phone interview will last 1 hour.

Interview estimates are based on applications of similar instruments. The hours stated also account for time spent recruiting.

The total burden hour request for this data collection is 61 hours.

Table A.12.A Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of responses per respondent	Average burden per response (in hours)	Total Burden (in hours)
School nurses, counselors, psychologists, and school administrators	Screening Instrument for Nurses, Counselors, Psychologists, and Administrators	96	1	10/60	16
School nurses, counselors, and psychologists	Interview Guide: Concept Testing for TBI Education Materials (Interviews with School Health Professionals)	30	1	1	30
School administrators	Moderator's Guide for In-Depth Interviews for Administrators	15	1	1	15
<b>Total</b>					<b>61</b>

B. The financial burden on participants will be minimized. Interviews will be scheduled at the convenience of participants, i.e., they can choose to conduct the discussions during work hours, if that is appropriate, or they can choose to be interviewed after work.

Table A.12.B. Estimated Annualized Respondent Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
School Nurses	10	18.24	182.40
School Counselors	10	23.77	237.70
School Psychologists	10	29.91	299.10
School Administrators	15	33.32	499.80
<b>Total</b>	<b>45</b>		<b>\$1,219.00</b>

\*Based on average hourly rate for May 2007. Bureau of Labor Statistics.

[http://www.bls.gov/oes/current/oes\\_nat.htm#b11-0000](http://www.bls.gov/oes/current/oes_nat.htm#b11-0000)

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

There is no other burden to respondents and record keepers.

### A.14. Annualized Cost to the Government

The direct cost to the Government will be \$52,685. All data collection will be implemented by vendors and overseen by the CDC project coordinator. The project will take place over three months. The costs are as follows for the implementation of concept and message testing:

**Table A.14.A. Annualized Cost (45 in-depth interviews)**

	<b>Hours</b>	<b>Hourly rate</b>	<b>Cost at hourly rate</b>	<b>Other costs*</b>	<b>Total</b>
Contractor	423	\$46.79	\$19,792	\$30,183	\$49,975
FTE	70	\$38.71	\$2,710	\$0	\$2,710
<b>Total</b>	<b>493</b>	<b>\$85.50</b>	<b>\$22,502</b>	<b>\$30,183</b>	<b>\$52,685</b>

\*Includes telephone, translation, incentives, transcriptions

### A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

### A.16. Plans for Calculation and Publication and Project Time Schedule

This IC includes qualitative analyses through thematic analysis. As no quantitative data will be collected, no complex analytic techniques will be used.

After testing the messages and materials in this project, the final versions will be available on CDC's website and distributed to partners, states, and the public. Results of the testing may be published, presented at conferences, and/or shared with other health professionals as appropriate. The project schedule is as follows:

**Table A.16.A. Project Schedule**

<b>Activity/Deliverable</b>	<b>Target Date</b>
Begin recruitment	3 weeks after OMB approval
Conduct research	4-8 weeks after OMB approval
Topline report to CDC	10 weeks after OMB approval

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

CDC will display the OMB control number and expiration date in the upper right-hand corner of all data collection instruments.

**A.18. Exceptions to Certificate in for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

**B. Collections of Information Employing Statistical Methods**

This is qualitative data collection. Statistical methods will not be used.