Attachment 6

IRB Exemption Application and Approval

AED SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH REVIEW
IRB NOTIFICATION OF RESEARCH REQUEST

Title of Research Activity: Traumatic Brain Injury Educational Materials Testing with School Health Professionals

AED Project Number: 3790-008-02

I) Key Personnel Information

AED Research Lead/ Principal Investigator			
Name:	Elyse Levine, Ph.D.	E-mail:	elevine@aed.org
Group/Center:	Center for Health Communication	Phone:	(202) 884-8913
Project Director			
Name:	Rosanne Hoffman	E-mail:	rhoffman@aed.org
		Phone:	(202) 884-8719
Center Director			
Name:	Carol Schechter	E-mail:	cschecht@aed.org
		Phone:	(202) 884-8931

II) Certification of Human Participant Protections Education

List all AED team members (e.g., co-investigators, data collectors, data analysts), as well as any other staff employed or funded by AED to conduct the activity (e.g., consultants). If there are more than ten names, attach a separate sheet.

Name of Research Team Member	Role in Research Activity	Online Training Certificate
1. Elyse Levine	Principal investigator	☒ On file ☐ Attached
2. Rosanne Hoffman	Project director	☒ On file ☐ Attached
3. Derek Inokuchi	Data Analyst	☒ On file ☐ Attached
4. Bonny Bloodgood	Data Analyst	☒ On file ☐ Attached
5. Sondra Dietz	Data Analyst	☒ On file ☐ Attached
6. Elyse Cohen	Project staff	☒ On file ☐ Attached

All research team members must have a training certificate verifying completion of the required human participant protections education module either on file with the AED Research Integrity Officer or attached to this form. The module is available online at: http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

III) Research Funding

Source of Funding: ☒ US Government ☐ Non-US Government	
Name of Funder/Sponsor:	CDC/NCIPC (National Center for Injury Prevention and Control)
Contract/Grant Number:	200-2007-20009
Name of Program/Technical Officer : Telephone: Email:	Kelly Sarmiento (770) 488-1384 egz8@cdc.gov

AED SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH REVIEW
IRB EXEMPTION REVIEW

IV) IRB Exemption Criteria

1. The Code of Federal Regulations sets out a set of situations where research may be exempted from full IRB review. Which of the following categories qualifies this research activity as eligible for exemption? (Check all categories that apply)

   Note: At least one of the following must be checked for IRB exemption to be considered.

☐	Research will be conducted in established or commonly accepted educational settings, involving normal educational practices. For example, it would include a comparison of the effectiveness of two generally accepted instructional strategies.
☒	Research will involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior. (Exemption will not be granted if the information is recorded in a manner in which the subject can be identified, AND disclosure would place the subject at risk of criminal or civil liability or be damaging to financial standing, employability, or reputation. This does not apply where the subjects are children except where it involves passive observation of public behavior.)
☐	Research will involve the use of educational tests, survey procedures, interview procedures or observation of public behavior where subjects are elected or appointed officials or candidates for public office. (Note: "Public Official" is not broadly defined.)
☐	Research involves the collection or study of EXISTING data, documents, records, or specimens if the sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers or codes. (Note: Even brief use of identifier or code disqualifies the exemption.)
☐	Research and/or demonstration program is designed to study, evaluate, or examine Federal public benefit or service programs. (The research must be sponsored by the program/government and approved at a high level within the organization. This is a very narrow exemption that will rarely apply.)
☐	Research includes a taste and food quality evaluation and consumer acceptance study involving wholesome foods without additives or with additives or chemicals below established "safe" levels.

2. Do any of the following limitations on exemptions apply to this research activity? (Check all that apply)

   Note: If any of the following limitations apply to this research activity it does not qualify for IRB exemption, and full IRB review is required. If you have determined that your research does not apply for exemption, please contact the AED Research Integrity Officer: Bill Smith at bsmith@aed.org or Olivia Marinescu at omarines@aed.org or at 202-884-8748.

☐	Research poses greater than *minimal risk* to participants[1].
☐	Research involves personal records (medical, academic, etc.) directly or indirectly identifiable.
☐	Research involves personal records (medical, academic, etc.) used without written consent.
☐	Research data (quantitative or qualitative) are directly or indirectly identifiable (e.g., including videotaping).
X	Research data from participants are used without written consent.
☐	Research involves participants not competent to provide informed consent.
☐	Research involves participants confined in a correctional or detention facility.
☐	Research involves: a) interaction with children (under the age of 18); b) obtaining identifiable private information about children through surveys or interviews of others; or c) observations of children where the researcher is involved in the actions being observed.
☐	Research involves pregnant women, fetuses or human in vitro fertilization.

Research will be conducted over the telephone. Participants will be asked to provide verbal consent during the screening process. Participants will be reminded of the consent information at the beginning of the telephone interview. Participants will not be asked to provide written consent.

[1] *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

AED SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH REVIEW
IRB EXEMPTION REVIEW

V) Description of the Research

1. What is AED's role in this research activity (Check all that apply)

☒	Research design
☒	Developing research instruments and/or protocols
☒	Conducting data collection
☒	Observing the data collection
☒	Managing and/or analyzing data
☒	Reporting and/or presentation of research findings
☐	Other (please describe):

2. Provide a brief description of the research. Include relevant background information, research objectives, proposed methodology, subject population, recruitment procedures, and consent process.

Background Information
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 (e.g., 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.

The proposed research includes conducting a total of 45 in-depth telephone interviews with school health professionals and administrators. School health professionals will consist of school nurses, counselors, and psychologists, while administrators primarily will be school principals, vice-principals, and superintendents.

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

Proposed Methodology
Data from selected caregivers will be collected by means of in-depth interviews conducted over the telephone. Interviews will include school health professionals and administrators from across the country. Two interview guides have been created. One was created for school health professionals (see Appendix 1) and one was created for school administrators (see Appendix 2). Both interview guides contain the same topics but have modified questions for the participant level (e.g., administrators will be asked about providing these materials to their staff instead of

personally using the materials).

Each interview is expected to last less than 60 minutes. All interviews will consist of the following elements:
- Discussion of health education roles within the school;
- Review of educational materials related to traumatic brain injury; and
- Dissemination of materials.

Trained interviewers will conduct the interviews and analyze the data. Up to 3 additional observers may listen to the interviews as they are being conducted. Each interview will be audiotaped and transcribed for analysis.

Participants will be paid a cash incentive of $75, which is commensurate with the rate for participation of health professionals and administrators.

Subject Population
Interview participants will be school health professional (school nurses, counselors, or psychologists) and school administrators. 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 traumatic brain injury

In addition, in order to participate, participants must be willing to be observed and audiotaped, although their identity will remain confidential. The full screening instrument to be used is included as Appendix 3.

Recruitment Procedures
A professional recruitment vendor will be contracted to identify, screen, and schedule participants. The vendor will use their existing database of participants, and may also partner with school districts or professional associations to recruit participants.

Consent Process
Participants will consent to the interview verbally, over the phone. This will take place immediately following the screening process. When someone qualifies to participate, the recruiter will read a consent statement and ask the participant to state their name and verbally agree to the terms outlined. Participants will be reminded of the informed consent terms at the beginning of their interview. The consent language can be found at the end of the screening instrument (Appendix 3).

3. Describe how confidentiality will be maintained including where data will be stored and who will have access. If confidentiality will be not maintained please explain why you believe confidentiality is not necessary.

In order to ensure confidentiality is maintained, AED will:
- Maintain no identifiers connecting any data collected to any particular participant; neither will it provide any personal identifiers to CDC or others; firms which conduct recruiting and host the sessions will be required to not provide personal identifiers to AED or CDC.
- 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.
- Develop a report in an agreed-upon format summarizing the responses provided by participants; the report will contain no personal identifiers, i.e., information sufficient to determine the identity of any participant (such as full name or address).
- Retain records, audio recordings, and transcripts for three years, then burn, shred, or otherwise destroy them.

AED SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH REVIEW
IRB EXEMPTION REVIEW

VI) Principal Investigator Assurance

As Principal Investigator, I certify that to the best of my knowledge:

The information provided for on all pages is correct and no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents and I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to changes in cooperating investigators, any change in procedure, or changes requested by agency in the case of externally funded research). I will comply with IRB and AED policies for conducting ethical research and I will be responsible for ensuring that my co-investigator(s)/student researcher(s) comply with this protocol. Any unexpected, adverse, or otherwise significant events in the course of this research activity will be promptly reported to the AED Research Integrity Officer.

Elyse Levine — 9/16/08

Signature of AED Research Lead/ Principal Investigator — Date

Carol Ann for Rosanne Hoffman — 9/16/08

Signature of Project Director — Date

Carol Ann — 9/16/08

Signature of Center Director — Date

AED Research Integrity Officer: Please indicate the AED IRB exemption request decision by checking the appropriate box below. If you modify or deny this request, please indicate the basis for the decision in an attachment.

- ☑ Request Approved
- ☐ Request Approved as Modified (comments attached)
- ☐ Request Denied (comments attached)

Signature of AED Research Integrity Officer — Date 9/18/08