Attachment G AED IRB Review

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

Title of Research Activity: Health Hazard Evaluation Program Customer Survey and Focus Groups

AED Project Number: 3790-002

I) Key Personnel Information

AED Research Lead/ Principal Investigator			
Name:	Tom Lehman	E-mail:	tlehman@aed.org
Group/Center:	CSMBC	Phone:	X8863
Project Director			
Name:	Tom Lehman	E-mail:	tlehman@aed.org
	CSMBC	Phone:	X8863
Center Director			
Name:	Cate Cowan	E-mail:	ccowan@aed.org
	CSMBC	Phone:	X8902

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. Tom Lehman	Instrument development, data analysis and reporting	☒ On file ☐ Attached
2. Chloe Kremidas	Instrument development data analysis and reporting	☒ On file ☐ Attached
3. Joy Pritchett	Instrument development data analysis and reporting	☒ On file ☐ Attached
4.		☐ On file ☐ Attached
5.		☐ On file ☐ Attached
6.		☐ On file ☐ Attached
7.		☐ On file ☐ Attached
8.		☐ On file ☐ Attached
9.		☐ On file ☐ Attached
10.		☐ 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:	Centers for Disease Control and Prevention
Contract/Grant Number:	200-2007-20009, Order 0002
Name of Program/Technical Officer : Telephone: Email:	Kenneth Wallingford 513-841-4327 kmw2@CDC.GOV

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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).
☐	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.

[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.

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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.

AED will develop a survey to assess knowledge, attitudes, and behaviors of potential HHE users. The survey will be electronically implemented and designed to take approximately 10 minutes to complete via the Web. The evaluation questions that have been collaboratively developed with CDC/NIOSH to provide the focus of the survey are:

1. What is customer awareness and understanding of HHE program resources and capabilities?
2. What are the best methods and channels for the HHE program to disseminate available resources and occupational safety and health-related technical information?
3. What is the most useful occupational safety and health communication products reported?
4. What are the perceived barriers to using HHE program resources?
5. What are the perceived motivators to encourage the use of HHE program resources?
6. What are the perceived top three occupational safety and health concerns reported?

The survey will be administered to achieve statistical power between and within the two sectors of interest (Food and Kindred Products Manufacturing and Services to Buildings and Dwellings) and it will sample managers, supervisors, and workers in small businesses with 10-250 employees. The sample will be obtained by randomly selecting 5000 potential respondents from commercially purchased lists of contact information that includes the name, employer name, mailing address and e-mail address for each potential survey respondent. Systematic sampling procedures will be used so that equal numbers of respondents from each of the two sectors are initially contacted. In addition, within each sector AED will aim to balance the number of persons contacted across sub-sectors so that roughly equal numbers of respondents from within each sub-sector participate. Thus, 278 potential respondents will be contacted from each of the 9 sub-sectors that comprise Food and Kindred Products Manufacturing and 417 potential respondents will be contacted from each of the 6 sub-sectors in Services to Buildings and Dwellings.

Survey respondents are advised in the survey invitation and instructions that participation is voluntary; all responses will be kept confidential; responses will not be disclosed to anyone outside CDC/NIOSH or AED except as required by law; data will be provided to CDC/NIOSH in aggregate form only; any potentially identifying information will be removed; any question may be skipped and they may stop at any time. Completion of the survey is regarded as consent to these procedures.
Focus group respondents provide their consent by reading the "About this project" statement and signing a consent document.

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.

For the customer survey, no personal identifiers will be collected. For the customer focus groups, AED will subcontract with professional focus group facilities to conduct the focus group interviews. Each professional facility will screen and schedule the respondents. All identifying or potentially identifying information will be maintained at the focus group facility in its proprietary files, and will not be accessible to CDC/NIOSH staff or AED staff. All information provided by respondents will be maintained by the facility in a confidential manner, unless compelled by law. The customer survey and focus group data files that are delivered to AED or CDC/NIOSH will be analyzed in the aggregate and no individual respondents will be identified.

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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.

Thomas C. Wilmer — 3/26/08

Signature of AED Research Lead/ Principal Investigator — Date

Thomas C. Wilmer — 3/26/08

Signature of Project Director — Date

[signature] — 3·26·08

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.

- [x] Request Approved
- [ ] Request Approved as Modified (comments attached)
- [ ] Request Denied (comments attached)

[signature]

Signature of AED Research Integrity Officer — Date