Appendix 2: IRB Exemption Review

AED
Academy for Educational Development

Institutional Review Board Protocol Review

January 22, 2009

From: Cory Heyman, Research Integrity Office

To: Elyse Levine, Principal Investigator
A. Cornelius Baker, Project Director
Carol Schechter, Center Director

Re: AED Project 3727-0202, Self-Administered Customer Satisfaction Surveys of Meetings and Conference Sessions

I have reviewed the IRB Protocol submitted for the above named project and determined it to be exempt; expedited or full IRB review is not required. Based on the protocol submitted, I conclude that the project poses minimal risk to participants and utilizes appropriate methods to ensure that the responses of the participants cannot be linked to the data collected, either directly or indirectly. In addition, appropriate procedures to ensure participant confidentiality are utilized.

Please let me know if any aspect of the research process changes to the extent that further review is necessary. Good luck with your project!

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

Title of Research Activity: Self-Administered Customer Satisfaction Surveys of Meetings and Conference Sessions

AED Project Number: 3727-0202

I) Key Personnel Information

AED Research Lead/ Principal Investigator			
Name:	Elyse Levine	E-mail:	elevine@aed.org
Group/Center:	CHC	Phone:	X 8913
Project Director			
Name:	A. Cornelius Baker	E-mail:	cbaker@aed.org
		Phone:	X 8612
Center Director			
Name:	Carol Schechter	E-mail:	cschecht@aed.org
		Phone:	X 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	PI	√ On file ☐ Attached
2. Bonny Bloodgood	Data analyst	√ On file ☐ Attached
3. Shea Van Horn	Data analyst	√ 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://phrp.nihtraining.com/users/login.php

III) Research Funding

Source of Funding: √ **US Government** ☐ Non-US Government	
Name of Funder/Sponsor:	National Institute of Allergy and Infectious Diseases
Contract/Grant Number:	GS:00F-0007M
Name of Program/Technical Officer : Telephone: Email:	Katherine Kripke, Ph.D. 301-594-2512 kripkek@niaid.nih.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).[1]
√	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.

*Consent will be implied by participants' completion of the questions

[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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This research will collect views of NHVREI partners and stakeholders who will not be identified. Individuals will not be asked to provide any personal identifying information and none of the questions or their responses would be damaging to their financial standing, employability or reputation. Respondents will not be asked to complete an informed consent form because it would be the only link to their personal identifying information. The survey will inform respondents that their responses are voluntary, that there are no consequences if they choose not to provide the information, and that their individual responses will be used by the NHVREI project and presenters only.

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. The National Institute of Allergy and Infectious Diseases' (NIAID) Division of AIDS funds HIV vaccine research. In an effort to develop support for HIV vaccine research, NIAID has created the NIAID HIV Vaccine Research Education Initiative (NHVREI) to foster knowledge of and support for HIV vaccine research. This research will focus on NHVREI partners and stakeholders that attend NHVREI meetings and/or conference sessions. Partners and stakeholders are gatekeepers of information who help to shape public perceptions of HIV vaccine research. NIAID plans to gather customer satisfaction information for its meetings and conference session presentations through a series of customer satisfaction surveys (CSS) with partners and stakeholders.

Research objectives. The purpose of this formative research is to determine the usefulness of NHVREI meetings and/or conference sessions and identify suggestions for refining content of future activities. By conducting CSSs with partners and stakeholders, NIAID will be able to better meet the needs of partners and stakeholders (see Participant Questionnaire attached as Appendix 1). Surveys would be used to elicit the following information at the conclusion of meetings or conference sessions:

- The extent to which participants found the meeting content to be useful;
- Outstanding questions that were not addressed at the meeting;
- The extent to which participants were satisfied with meeting logistics (location, time, facilities); and
- Suggestions for improving future meetings.

Proposed methodology. NIAID plans to conduct customer satisfaction surveys with NHVREI partners and stakeholders that attend NHVREI meetings and/or conference sessions.

NHVREI will conduct up to 1610 surveys over the next two years, ending February 28, 2011. NHVREI plans to survey NHVREI partners and stakeholders at all appropriate meetings and/or conference sessions; specific dates and locations of meetings and conference sessions are still to be determined.

The surveys will be distributed to partners and stakeholders attending NHVREI meeting and/or conference sessions. It will take respondents up to 12 minutes to complete the survey. All surveys will be completed and returned to a designated location.
Each survey will:

A. Gauge usefulness:
   - Of the meeting and/or conference session
   - Of individual presentations
   - Of meeting materials

B. Gauge satisfaction:

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- With logistics
- With meeting overall

C. Identify:
- Meeting and/or conference session high points
- Suggestions for improvement for meeting and/or conference session
- Outstanding questions
- Additional meeting and/or conference session topics
- Intentions to attend the meeting again
- Additional comments

Subject Population. The respondents sought for this research consist of up to 1610 individuals from NHVREI partners and stakeholders attending NHVREI meetings and/or conference sessions. All individuals attending these sessions will be given a survey.

Incentive. Participants will not receive any payment or gift for completion of the survey. Participation will be voluntary and respondents will not be re-contacted.

Analysis. Mean responses to closed-ended items will be tabulated, and responses to open-ended questions will be noted and considered for planning future meetings.

Consent. The survey will inform respondents that their responses are voluntary, that there are no consequences if they choose not to provide the information, and that their individual responses will be used by the NHVREI project and presenters only. Written informed consent from participants is not considered necessary, especially since it would involve collecting unnecessary personal identifying information.

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.

Respondents will not be asked to provide personal identifying information. For this reason, no assurance of privacy or confidentiality is required.

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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.

Elyse Laine — Signature of AED Research Lead/ Principal Investigator

Jan. 21/09 — Date

Signature of Project Director

1/21/09 — Date

Signature of Center Director

1/21/09 — 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

22 Jan 2009 — Date