AED SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH REVIEW REQUEST: NOTIFICATION TO AED INSITUTIONAL REVIEW BOARD (IRB)

Title of Research Project, Study, or Activity: Self-Administered Customer Satisfaction Surveys of Meetings and Conference Sessions

AED Project Number: __3727-0202_____

AED Group: ___Social Change_____

AED Center: ___COACH/CHC_____

I) Key Personnel Information

AED Research Lead and/or Principal Investigator	
Name: B onny Bloodgood	E-mail: bbloodgood@aed.org Phone: X 8176
Project Director	
Name: Cornelius Baker	E-mail: cbaker@aed.org Phone: X8845
AED Center Director	
Name: C arol Schechter (CHC)	E-mail: cshecht@aed.org Phone: X8931

II) Certification of Human Subjects Protections Education

List all AED key team members (e.g., project directors, principal investigators, data collectors, data analysts), as well as any other key staff employed or funded by AED (e.g., contractors, consultants, staff from partner organizations) to conduct the research tasks and activities. If there are more than ten names, attach a separate sheet. It is expected that all key staff will have obtained certification. In the case of certain support staff (e.g., field-based data collectors) who do not have certification, the PI or project director must guarantee that adequate orientation and education in human subjects protections has been provided to such staff (see Section VI below).

Name of Research Team Member	Role in Research Activity	Online Training Certificate
1. Bonny Bloodgood	PI	☒ On file ☐ Attached
2. Shea Van Horn	Data analyst	☒ On file ☐ Attached
3.		☐ 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 key and lead research team members must have a training certificate, current within the past 3 years, verifying completion of the required human subjects 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.

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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 Funder's Program/Technical Officer : Telephone: Email:	Katherine Kripke, Ph.D. 301-594-2512 kripkek@niaid.nih.gov

IV) IRB Exemption Criteria

1. The Code of Federal Regulations sets out a set of situations where research may be exempted from either an expedited or 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 <u>not</u> 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.

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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 either an expedited or full IRB review will be required. An expedited review can be conducted by AED's Research Integrity Officer or a member of AED's IRB Council, while a full review will need to be conducted by AED's IRB Contract Provider. You may provide a justification for exemption if any box below is checked. You may contact the AED Research Integrity Officer, Richard Sawyer at rsawyer@aed.org or 202-884-8868 or Sandi Gollob, IRB Program Associate, at sgollob@aed.org or at 884-3762.

☐	Research poses greater than *minimal risk* to participants[1]. Minimal risk may include collecting data and information from participants that could be considered personal or sensitive (e.g., beliefs, attitudes, or behaviors related to sexual practices, reproductive health; information about participants' health status).
☐	Research involves personal records (medical, academic, etc.) in which human subjects could be directly or indirectly identifiable.
☐	Research involves personal records (medical, academic, etc.) used without written consent from research participants.
☐	Research data (quantitative or qualitative) from participants are directly or indirectly identifiable (e.g., videotaping).
☒	Research data from participants are used without written consent from participants.
☐	Research involves participants who may not be competent (e.g., individuals with health or mental health problems, cognitive limitations, neurologic conditions, or substance abuse history) 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 other data collection methods; or c) observations of children where the researcher is involved in the behaviors or 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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V) Description of the Research

1. What is AED's role in this research study, project or activity (*Check all that apply*)

☒	Research design
☒	Developing research instruments and/or data collection protocols
☒	Designing, managing, and/or directly conducting data collection
☒	Observing the data collection
☒	Managing and/or analyzing data
☒	Reporting and/or presenting research findings in written or oral formats
☐	Other (please describe):

2. Provide a BRIEF description of the research. Include relevant background information, research objectives, research design, methodology (subject population, sampling, participant recruitment procedures, instrument design), research participant burden (e.g., time required; potential risks in participation), and informed consent process.

Background Information. The National Institute of Allergy and Infectious Diseases' (NIAID) Division of AIDS funds HIV vaccine research and other biomedical prevention research. In an effort to develop support for HIV vaccine research, NIAID sponsors meetings and conferences to increase awareness of HIV vaccine and other biomedical prevention research. This research will focus on individuals that attend NIAID-sponsored meetings and/or conference sessions. 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 NIAID-sponsored meetings and/or conference sessions and identify suggestions for refining content of future activities. By conducting CSSs, 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 individuals that attend its sponsored meetings and/or conference sessions.

Up to 2315 surveys will be conducted over the next three years, ending April 30, 2014. Individuals will be surveyed 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 at meetings 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:
   - 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 2315 individuals attending NIAID-sponsored 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 NIAID's funded contractor 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 human subjects protections, informed consent, and confidentiality will be maintained. Also, briefly describe where data will be stored and who will have access to the data. If informed consent and confidentiality will not be maintained please provide a rationale based on the needs of the research.

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/Project Director Assurance

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

The information provided in this document and any supporting documents is correct and no other research procedures related to human subjects protections will be used in this research project or activity. I agree to conduct this research as described in this and any attached supporting documents and I will request and receive approval from the AED IRB for any significant changes that impact human subjects protections prior to implementing the changes (including but not limited to changes in key research lead staff, any change in research and data collection procedures, or changes requested by the funding agency that affect the research).

I will comply with AED IRB policies for conducting ethical research and will be responsible for ensuring that all research team members and staff comply with human subjects protections. I will provide the necessary human subjects protections orientation and education to staff, including any support staff who may not have the NIH certification (e.g., recruitment staff, data collectors). Any unexpected, adverse, or otherwise significant events in the course of this research project or activity will be promptly reported to the AED Research Integrity Officer.

Amy Bordford — 5-3-11

Signature of AED Research Lead / Principal Investigator — Date

Carol Schlecter — 5-3-11

Signature of ~~Project~~ Center Director — Date

5-3-11

Signature of ~~Center~~ Project Director — Date

Stacey Little on behalf of Cornelius Baker

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AED Research Integrity Officer or AED IRB Council Member Designee: Please indicate the AED research review IRB category status decision by checking the appropriate box below. If you modify or deny this request, please indicate the basis for the decision on this form or in an attachment. You may also make suggested revisions to this document and any supporting documents electronically using the Track Changes feature in Word.

- ☐ Exempted, Request Approved
- ☐ Exempted, Request Approved with Modifications
- ☑ Expedited, Request Approved
- ☐ Expedited, Request Approved with Modifications
- ☐ Full IRB Review Required with AED IRB Contract Provider (Chesapeake Research Review Inc.)
- ☐ Request Denied (comments attached)

Richard Sawyer — Signature of AED Research Integrity Officer or IRB Council Member

5-4-2011 — Date

Form Approval
OMB No. 0925-0585-06
Expires 04/30/2014

Appendix 1: Participant Questionnaire

Form Approval
OMB No. 0925-0585-06
Expires 04/30/2014

[Title of Meeting/Session]
[DATE]
Participant Questionnaire

Instructions:

- Please do not write your name on this sheet.
- Completion of this questionnaire is voluntary and there are no consequences for choosing not to participate. Participants are not required to complete all questions, and may stop taking the survey at any time.
- Responses will be used by NIAID **[, name of contractor/grantee,]** and presenters to improve future **[meetings/sessions/presentations]**.
- After completion, please return the form to **[designated location]**.

Please circle the number that represents your response to the statements below:

	Strongly Disagree				**Strongly Agree**
Overall, the information presented was useful	1	2	3	4	5
*Information presented by [1st presenter] was useful	1	2	3	4	5
The materials and handouts were helpful	1	2	3	4	5
I was satisfied with the meeting logistics (location, facilities, etc.)	1	2	3	4	5
I would recommend this meeting/workshop to my colleagues	1	2	3	4	5
This meeting/workshop helped me better understand HIV prevention research	1	2	3	4	5

* Question is repeated for each presenter

Please answer the following questions:

1. What did you like *most* about the meeting/workshop?

2. What suggestions do you have for improving the meeting/workshop/presentation? (Consider timing, facility, technology, opportunity for discussion/questions)

3. Do you have any outstanding questions that were not addressed at the meeting/workshop? If so, please list below.

4. Was there any information not presented at the meeting that would be helpful to you to update your community members on HIV vaccine research and/or other HIV prevention research? If so, please explain.

5. (For annual meetings) Do you plan to attend this meeting next year? _____ (Yes or No)
(For standalone meetings/conference sessions) Would you be interested in attending more meetings/sessions like this in the future? _____ (Yes or No)

   If your answer is "No," please explain why.

6. Additional Comments: