

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

III) Research Funding

Source of Funding: <input checked="" type="checkbox"/> US Government <input type="checkbox"/> 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:	Katherine Kripke, Ph.D. 301-594-2512
Email:	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.

<input type="checkbox"/>	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.
<input checked="" type="checkbox"/>	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.)
<input type="checkbox"/>	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.)
<input type="checkbox"/>	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.)
<input type="checkbox"/>	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.)
<input type="checkbox"/>	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.

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

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.

<input type="checkbox"/>	Research poses greater than <i>minimal risk</i> 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).
<input type="checkbox"/>	Research involves personal records (medical, academic, etc.) in which human subjects could be directly or indirectly identifiable.
<input type="checkbox"/>	Research involves personal records (medical, academic, etc.) used without written consent from research participants.
<input type="checkbox"/>	Research data (quantitative or qualitative) from participants are directly or indirectly identifiable (e.g., videotaping).
<input checked="" type="checkbox"/>	Research data from participants are used without written consent from participants.
<input type="checkbox"/>	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.
<input type="checkbox"/>	Research involves participants confined in a correctional or detention facility.
<input type="checkbox"/>	Research involves: a) interaction with children (under the age of 18); b) obtaining identifiable private information about children through surveys or interviews or other data collection methods; or c) observations of children where the researcher is involved in the behaviors or actions being observed.
<input type="checkbox"/>	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.

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

V) Description of the Research

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

<input checked="" type="checkbox"/>	Research design
<input checked="" type="checkbox"/>	Developing research instruments and/or data collection protocols
<input checked="" type="checkbox"/>	Designing, managing, and/or directly conducting data collection
<input checked="" type="checkbox"/>	Observing the data collection
<input checked="" type="checkbox"/>	Managing and/or analyzing data
<input checked="" type="checkbox"/>	Reporting and/or presenting research findings in written or oral formats
<input type="checkbox"/>	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

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

- 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.

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

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.



Signature of AED Research Lead / Principal Investigator

5-3-11

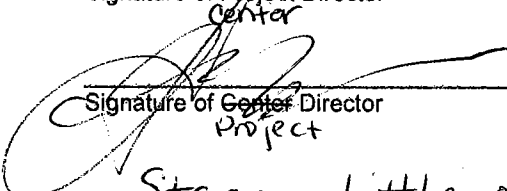
Date



Signature of Project Director
Center

5-3-11

Date


Signature of Center Director
Project

5-3-11

Date

Stacey Little on behalf of Cornelius Baker

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

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)


Signature of AED Research Integrity Officer or IRB Council Member

5-4-2011
Date

Appendix 1: Participant Questionnaire

**[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]**.

Public reporting burden for this collection of information is estimated to average 12 minutes per response. This time includes the length of time allotted to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0585). Do not return the completed form to this address.

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 [1 st 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?

