Appendix 7: IRB Exemption Review

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

Title of Research Activity: Focus Groups for Message and Materials Pretesting of NIAID's HIV Vaccine Research Education Initiative

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.

[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.

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. As part of NHVREI, local and national partner non-governmental organizations have committed to share information and educational materials about HIV vaccine research. NIAID developed educational materials in 2006 to meet this need, however, major events in vaccine research have occurred since then. NIAID does not know the extent to which these materials remain effective with target audiences.

Research objectives.

- Assess community values relative to HIV vaccine research
- Explore current HIV vaccine research knowledge and attitudes
- Prioritize barriers to HIV vaccine research
- Explore perceived benefits of participating, or supporting participation in, HIV vaccine trials
- Explore materials and messages used and resource needs
- Assess utility of current materials and messages; explore needs for additional materials and/or messages

Proposed methodology. NIAID plans to conduct formative research using focus groups with individuals from three populations: African Americans, Hispanics, and men from all racial and ethnic groups who have sex with men.

A total of up to 16 groups will be conducted. Groups will be segmented by race/ethnicity and sexual orientation (Heterosexual African Americans, Heterosexual Hispanics, or men of any race/ethnicity who have sex with men). Heterosexual African American and Heterosexual Hispanic groups will be grouped by gender.

Locations of focus groups have been selected to reach individuals from the three priority populations. The cities selected are New York, NY; Miami, FL; Atlanta, GA, and Oakland, CA.

Each focus group is expected to last less than 120 minutes. The focus groups will consist of the following elements:

A. Assess current HIV vaccine research knowledge and attitudes
   - Identify and prioritize existing myths/barriers
B. Explore preferences for materials development and dissemination
   - Current and preferred sources of HIV vaccine research information
   - Preferred channels for HIV vaccine research information
C. Explore concepts/themes
D. Test "Be the Generation" materials currently in use

A draft of the moderator's guide is included in Appendix A. A professional moderator will guide the discussion of all focus groups. Up to six observers from NHVREI and AED may observe the groups from behind a one-way mirror. A NHVREI representative will be available to answer questions at the completion of each discussion. All focus groups will be audiotaped, and transcripts will be prepared from the audio recordings.

Subject Population. The respondents sought for this research consist of up to 144 individuals from the priority

audiences for the program (African Americans, Hispanics, and men from all racial and ethnic groups who have sex with men). Quota sampling will be used to select a sample of individuals who meet certain qualifications that reflect characteristics typical of the target audience.

Recruitment.
Recruiting will be handled by a market research firm experienced with these audiences, using a screener developed by AED. Screening will be conducted over the telephone. In screening participants for focus groups, recruiters will take care to ensure that only individuals meeting the recruitment criteria are invited to attend the groups (a copy of the screening instrument is included as Appendix B). For example, individuals will be excluded from participation if they:

- Are transgendered
- Are employed in the media or market research, health care, or public health fields
- Have participated in a focus group or market research study within the last six months

Participants will receive a $75 monetary incentive for participation. If recruits qualify to participate, they will be given the time and location of the focus group, and recruiters will confirm contact information for follow-up.

Consent. During screening (i.e., on the phone), participants will be informed about logistics of the focus groups, including that the groups will be audiotaped. When participants arrive at the focus group facility, they will be given an information sheet with an attached informed consent document (Appendix C); they will sign the informed consent document prior to participation in the focus group. Participants will keep the top sheet of the informed consent document, which includes a phone number to call for concerns about their participation.

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.

This data collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." While we cannot assure confidentiality, standard measures will be taken to keep data securely stored (see attached AED Guidelines). Participants will be informed that the information they provide will be kept private to the extent permitted by law. The participants will be identified by name and work place, but no personal records such as medical records, salary, or social security numbers will be collected for this research.

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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.

Signature of AED Research Lead/ Principal Investigator	Date

A. Gr... — Signature of Project Director

August 8, 2008 — Date

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

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VI) Principal Investigator Assurance

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

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Elyse Levine — Aug. 6/08

Signature of AED Research Lead/ Principal Investigator — Date

Carl Schlenker — 8/6/08

Signature of Project Director — Date

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 of AED Research Integrity Officer — 8/8/08 — Date