Appendix 4: IRB Exemption Review

AED
Academy for Educational Development

Institutional Review Board Protocol Review

February 10, 2010

From: Cory Heyman, Institutional Review Board Chair

To: Bonny Bloodgood, AED Research Lead
A. Cornelius Baker, Project Director
Carol Schechter, Center Director

Re: AED Project #3727-0202, Message and Materials Pretesting

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 research activity 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!

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IRB NOTIFICATION OF RESEARCH REQUEST

Title of Research Activity: Message and Materials Pretesting

AED Project Number: 3727-0202

I) Key Personnel Information

AED Research Lead/ Principal Investigator			
Name:	Bonny Bloodgood	E-mail:	bbloodgood@aed.org
Group/Center:	CHC	Phone:	X 8176
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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IRB EXEMPTION REVIEW

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: Cory Heyman or Ahlam Ghadry.

☐	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.

As per standard practices, online survey participants will be provided with informed consent information and will be asked a question that confirms that they have read and agree with the information.

[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, but recent research conducted by NIAID determined that new materials need to be developed. Research findings suggested a need for educational videos. Before going through the expense of creating new videos, NIAID would like to test concepts and existing videos.

Research objectives.
- Explore opinions of existing videos
- Explore opinions of draft concepts for new videos

Proposed methodology.
NIAID plans to conduct formative research using an online survey. The online survey will be conducted with up to 250 individuals from four hard-to-reach or minority populations that represent those US populations most highly affected by HIV/AIDS.

Each survey will last up to 25 minutes, including 5 minutes for screening. The survey will:
A. Review existing videos (two videos will be reviewed)
B. Review draft concepts for new videos (two storyboards/approaches will be reviewed)

The online survey is included as Appendix A. The online survey recruitment and hosting will be conducted by a subcontractor to AED. Participants will input screening and survey responses directly into a database. A report will be generated from the results to help NIAID and AED further refine educational videos and video concepts. Data from the surveys will be analyzed in SPSS.

Subject Population.
Participants will include NHVREI priority populations (Black/African-American, Hispanic/Latino, men from all racial/ethnic groups who have sex with men (MSM), and transgender individuals (male-to-female only).

Recruitment.
Recruiting will be handled by an online survey research firm, using a screener developed by NIAID/AED. Screening will be conducted online through a programmed screening survey. In screening participants for the survey, recruiters will take care to ensure that only individuals meeting the recruitment criteria are invited to complete the survey (see Appendices A). Individuals who complete the survey will receive an incentive valuing $10.

Consent.
Participants will be provided with informed consent information after they have been invited to complete the survey. Participants will be asked if they have read and agree with the informed consent information. Only those who agree with the information will be able to complete the survey. Participants can choose to stop answering questions at any

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time, but are told that they need to complete the survey to receive the incentive.

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. Participants will be informed that the information they provide will be kept private to the extent permitted by law. No personal records such as medical records, salary, or social security numbers will be collected for this research. NIAID and AED will not have access to any personally identifiable information.

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.

Bonny Bordgord — 2-4-10

Signature of AED Research Lead/ Principal Investigator — Date

Carol Johnston on behalf of Cornelius Baker — 2-4-10

Signature of Project Director — Date

Carol Johnston — 2-4-10

Signature of Center Director — Date

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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

10 Feb 2010
Date