PRETESTING OF NIAID'S HIV VACCINE RESEARCH EDUCATION INITIATIVE COMMUNICATION MESSAGES

Mini Supporting Statement

Focus Groups and Intercept Interviews for Message and Materials Pretesting

OMB # 0925-0585 (expiration date, 2/28/2011)

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Section A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Institute of Allergy and Infectious Diseases (NIAID) supports basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses, including illness from human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). This research will include a series of focus groups (FGs) and intercept interviews (IIs) with individuals from four hard-to-reach or minority 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) that represent those US populations most highly affected by HIV/AIDS. See Table 1-1 for a breakdown of respondents by research method.

Table 1-1. Respondent Audiences by Research Method

Audience	Focus Groups	Intercept Interviews
African American Men (Heterosexual)	1 group (9 participants)	40 intercepts
African American Women (Heterosexual)	1 group (9 participants)	40 intercepts
Hispanic/Latino Men (Heterosexual)	1 group (Bilingual: English and Spanish) (9 participants)	40 intercepts (20 English, 20 Spanish)
Hispanic/Latina Women (Heterosexual)	1 group (Bilingual: English and Spanish) (9 participants)	40 intercepts (20 English, 20 Spanish)
MSM: African American	1 group (9 participants)	30 intercepts
MSM: Hispanic/Latino	1 group (9 participants)	20 intercepts
MSM: Caucasian	-	20 intercepts
MSM: Any race/ethnicity	1 group (9 participants)	10 intercepts
Transgender Individuals (Male-to-Female only)	-	10 intercepts
TOTAL	7 groups (63 participants)	250 intercepts

The required strategies for increasing individual willingness to support or participate in HIV vaccine research have been identified through earlier FGs. These next FGs and IIs are intended to pretest NIAID's newly developed materials and messages and provide NIAID with guidance for improving its education initiative that aims to increase awareness of and support for HIV vaccine research.

A.2. Purposes and Use of the Information

The purpose of this formative research is to guide development of HIV vaccine research educational materials for the NIAID HIV Vaccine Research Education Initiative (NHVREI). By conducting FGs and IIs with individuals, NIAID will be able to refine newly developed NHVREI materials to more effectively increase HIV vaccine research knowledge and awareness. The FGs will allow NIAID to gain in-depth feedback about the materials from a small number of people (n=63). The IIs will allow NIAID to gather feedback about attention-getting components of the materials (e.g., headlines, colors, images) and feedback on key sentences in the materials from a larger number of people (n=250).

These FGs and IIs will enable NIAID to:

- Understand the attitudes, beliefs, and behaviors of priority populations in order to refine effective communication materials for the priority populations;
- Gain feedback about the design, format, and content of newly developed educational materials that are intended to influence the priority populations' attitudes and behavior to support HIV vaccine research; and
- Expend limited program resource dollars wisely and effectively by creating materials that best meet the priority populations' specific needs.

A.3. Use of Information Technology and Burden Reduction

The use of technology such as online surveys is not possible, as the information sought during interviews requires responses elicited from semi-structured FGs and open-ended questions, rather than from a structured questionnaire. In-person interviews provide an opportunity to note non-verbal responses, which is important given the topic. Additionally, our first phase of research demonstrated that some individuals in the priority populations do not use the Internet.

A.4. Efforts to Identify Duplication and Use of Similar Information

This research seeks to assess the effectiveness of educational materials targeted toward communities disproportionately affected by HIV/AIDS and underrepresented in HIV vaccine trials. Between 2001 and 2003, NIAID conducted research with the same priority populations to assess the knowledge and attitudes surrounding HIV vaccine research.[1] NIAID used findings from the research to create themes, messages, and materials to encourage support of HIV vaccine trials. In September 2007, significant events in vaccine research, including the failure of the most advanced HIV vaccine candidate to date, generated publicity that may have changed public opinion significantly from that which was studied in 2001 and 2003. A series of 24 focus groups (OMB #0925-0585-02) was conducted in spring 2009 to inform NIAID about whether changes in awareness, attitudes, and knowledge have occurred among NHVREI priority populations, and if so, whether these changes necessitate revisions to current messaging and materials. The findings from that research suggest that existing messages and materials do not meet

[1] Allen MA, Liang TS, La Salvia T, et al. Assessing the attitudes, knowledge, and awareness of HIV vaccine research among adults in the United States. *J Acquir Immune Defic Syndr*. 2005.

current needs and revised messages and materials are required. NIAID would like to pretest the newly developed materials with the intended audiences. As NIAID is developing new materials, the FG and II research does not duplicate the previous data collections on this topic, and we are not aware of publications of other research that is duplicative of these information collections (see Focus Group Moderator's Guide attached as Appendix 1 and Intercept Interview Instrument attached as Appendix 2).

A.5. Impact on Small Businesses or Other Small Entities

No small businesses or entities such as community-based organizations or health care providers will be involved in these focus groups or intercept interviews.

A.6. Consequences of Collecting the Information Less Frequently

Participation will be voluntary and respondents will not be re-contacted. FGs are appropriate because they collect a large amount of information from several respondents during one brief discussion. IIs are appropriate because they collect focused information from many respondents in geographically dispersed areas.

A.7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5

Because NIAID's pretesting activities are primarily qualitative in nature, most results are not generalizable to the population at large or to the particular audience under study. However, the nature of pretesting is such that generalizability is not a critical feature; the emphasis is on obtaining timely, useful information that NIAID can use to refine new

messages and materials. FGs and IIs will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

A.8. Consultation Outside the Agency

NIAID completed the necessary 60-day and 30-day Federal Register notices during the generic clearance request (ICRAS: 0925-0585). NIH, along with other Public Health Service agencies, has been a leader in the development of methods for developing, testing, and disseminating health information. A number of outside health communications experts reviewed the plans contained herein for formative research and pretesting of communication materials to inform NIAID communications programs and their comments and suggestions have been incorporated into these data collection plans.

A.9. Explanation of any Payment or Gift to Respondents

Tokens of appreciation are commonly used in order to obtain focus group participation from those who may not otherwise participate. There is extensive literature to support the use of incentives, primarily monetary incentives, as a supplement or complement to other efforts of persuasion to ensure recruitment of a representative sample, especially among hard-to-reach and minority populations.[2,3] In studies for both commercial market research and social sciences, findings indicate that respondents who receive these tokens of appreciation provide valid input, and their inclusion makes for a more representative sample.

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[2] Singer E and Kulka RA. Paying respondents for survey participation. In Ver Ploeg M,.Moffitt RA, Citro CF (eds). Studies of Welfare Populations: Data collection and Research Issues. National Academy Press: Washington, DC 2001. Available at http://www.nap.edu/openbook/0309076234/html. Accessed on May 13, 2008.

[3] Kovac MD, Markesich J. Tiered incentive payments: getting the most bang for your buck. Presentation at the Annual Conference of the American Association for Public Research, 2002.

A monetary incentive of $75.00 is suggested for the focus group recruitment. ~~Based on experience, it may be necessary to increase the incentive to $90 in one or two of the groups if there is difficulty with recruitment with some populations in some locations.~~ This rate is requested for the following reasons:

- Eligibility criteria for focus group participants are specific. All FG respondents will consist of three hard-to-reach or minority populations (Black/African-American, Hispanic/Latino, and men from all racial/ethnic groups who have sex with men (MSM)), which represent those US populations most highly affected by HIV/AIDS. It is important to offer incentives sufficient to attract the needed participants.
- These focus groups have a specific subject matter, HIV vaccine research, and may include discussion of sensitive HIV-related topics. The primary purpose of this project is to enhance minority support for HIV vaccine research. HIV vaccine research is not supported in all communities, and individuals may not be interested in participating without an enticing incentive.
- Participants will be asked to travel to the focus group testing location, which involves transportation and parking expenses. The focus group will last approximately two hours and individuals may need to leave their jobs during business hours or arrange for childcare.

A monetary incentive of $10.00 is suggested for the intercept interview recruitment. This rate is requested for the following reasons:

- Eligibility criteria for intercept interview participants are specific. All II respondents will consist of four hard-to-reach or minority 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)), which represent those US populations most highly affected by HIV/AIDS. It is important to offer incentives sufficient to attract the needed participants.

- These intercept interviews have a specific subject matter, HIV vaccine research, and may include discussion of sensitive HIV-related topics. The primary purpose of this project is to enhance minority support for HIV vaccine research. HIV vaccine research is not supported in all communities, and individuals may not be interested in participating without an enticing incentive.
- Participants will be asked to respond to questions for up to 20 minutes.

A.10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality will be provided to respondents; however, NIAID and its contractor, AED, will follow best practices to minimize collection of identifying information and will keep data stored securely (see AED Guidelines attached as Appendix 3). A subcontractor familiar with AED's guidelines will be secured to recruit potential participants. Potential participants will be asked for specific demographic information (note that MSM and transgender participants will be recruited within communities and organizations serving these populations). NIAID and AED will receive participant first names and demographic characteristics (see Focus Group Screener attached as Appendix 4 and screening information in the Intercept Interview instrument attached as Appendix 2). NIAID/AED will not have access to personal contact or identifying information.

The 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," which is available at http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm (a confirmation from the NIH Privacy Officer is attached as Appendix 5). Individuals will be informed of the statutory authority for collecting the information. Further, they will be told that their responses are voluntary, that there are no consequences if they choose not to provide the information, and that their individual responses will not be disclosed to anyone but the researchers conducting the study, except as otherwise required by law (see Informed Consent Form for Focus Group Participants attached as Appendix 6 and Informed Consent Form for Intercept Interview Participants attached as Appendix 7).

This research has been approved for exemption from 45 CFR 46 by AED's Research Integrity Officer on the grounds that the protocol poses no risk to participants' financial standing, reputation, or employability (46.101(b)(2)) (see IRB Exemption Review attached as Appendix 8).

A.11. Justification for Sensitive Questions

Since NIAID's NHVREI communications focus on HIV/AIDS and participation in HIV vaccine research, there is a remote possibility that some participants may feel sensitive about discussing HIV/AIDS, a disease that can be transmitted through sexual contact or injection drug use. Participants will be informed of the purpose of the research and how their responses will be used to refine communications to encourage support for HIV vaccine research during recruitment (see Focus Group Screener in Appendix 4) and on

the informed consent form (attached as Appendix 6) for focus group participants and in the screener (see Intercept Interview Instrument attached as Appendix 2) and informed consent form (attached as Appendix 7) for intercept interview participants. The moderator will make it clear that participants do not have to respond to any question that makes them uncomfortable. Respondents will be informed that the information they share is voluntary and will be kept private to the extent permitted by law. The information will not become part of a system of records containing permanent identifiers that can be used for retrieval.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

Focus Groups:

The estimated time for the annual burden from implementing the focus group and intercept interview research is summarized in Table 12-1 below. The focus group annual burden is based on 7 focus groups consisting of 9 people each, for a total of 63 people (recruiting 77 individuals to have 63 attend the focus groups). The estimated time for the annual burden from implementing the intercept interview research is based on 300 individuals screened to complete 250 intercept interviews. The length of time for the sessions draws on the research contractor's extensive experience with similar focus groups and intercept interviews.

Table 12-1. Estimates of Hour Burden for Focus Groups and Intercept Interviews

Form Name	Total Number of Respondents	Frequency of Response	Average Time Per Response	Annual Hour Burden
Screener Instrument: Focus Groups	77	1	5/60 hours	6.42
Moderator's Guide: Focus groups	63	1	2 hours	126.0
Intercept Interview Instrument: Part 1- Screening	300	1	5/60 hours	25.00
Intercept Interview Instrument: Part 2- Research Questions	250	1	15/60 hours	62.50
TOTAL	377			219.92

Annualized costs for focus group and intercept interview research, summarized in Table 12-2 below, use the mean hourly wage for all occupations provided by the U.S. Department of Labor, Bureau of Labor Statistics.[4]

Table 12-2. Annualized Cost to Respondents for Focus Groups and Intercept Interviews

Type of Respondents	Hourly Wage Rate	Total Burden Hours	Respondent Cost
Lay public	$20.32	219.92	$4468.77

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital costs, operating costs, and/or maintenance costs to report.

[4] U.S. Dept. of Labor, Bureau of Labor Statistics. May 2008 National Occupational Employment and Wage Estimates, United States. Accessed on May 15, 2009 at http://www.bls.gov/oes/current/oes_nat.htm#b11-0000.

A.14. Estimates of Costs to the Federal Government

The total annual cost to the Federal Government reported here is an approximation. In the full supporting statement, it was estimated that the cost for the government for each FG study would be approximately $80,000 and $12,000 for each central location interview study. This estimate included the cost of study design, recruitment, moderator, and data collection. This particular study requests up to seven FGs be conducted with a total anticipated cost of $50,000 and 250 IIs with a total anticipated cost of $12,000. This research will have a small impact on the total cost of approximately $1,344,000 that was estimated in the full supporting document.

A.15. Explanation for Program Changes or Adjustments

No burden changes are requested. This is a new formative research study under the existing generic study titled “Pretesting of NIAID’S HIV Vaccine Research Education Initiative Communication Messages” (OMB #0925-0585). This represents the fourth sub-study, which, once approved, will be indicated by 0925-0585-04.

A.16. Plans for Tabulation and Publication and Project Time Schedule

This information collection does not require statistical analyses. FGs will be conducted within 8 weeks after OMB approval. We anticipate that it will take no more than 8 weeks to recruit participants and conduct 7 FGs. IIs will be conducted within 12 weeks after OMB approval. We anticipate that it will take no more than 12 weeks to complete 250 intercept interviews. Results for the FG and II study will be summarized within 2-4

weeks after the completion of the last interview. Selected findings will be used to develop or refine new HIV vaccine clinical research materials and messages.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

NIAID will display the OMB number and expiration date on upper right corner of participant informed consent forms.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

These FGs and IIs will comply with the requirements in 5 CFR 1320.9. No exceptions to certification are requested.

Section B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

Section B is not addressed in this individual information collection request under the generic clearance ICRAS: 0925-0585 because this particular information collection will not employ statistical methods.