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

Mini Supporting Statement

Focus Groups 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 focus on 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 and AIDS. The required strategies for increasing individual willingness to support or participate in HIV vaccine research have not been determined. In order to achieve this end, NIAID plans to pretest its communications strategies, concepts, and messages. This series of focus groups (FGs) with individuals from populations most affected by HIV in the United States will help NIAID better understand methods for communicating information about HIV vaccine research to these populations. The results of these FGs will 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 NIAID's development of HIV vaccine research educational materials for its HIV Vaccine Research and Education Initiative (NHVREI). By conducting FGs with individuals, NIAID will be able to develop new and

refine existing NHVREI materials to more effectively increase HIV vaccine research knowledge and awareness.

These FGs will enable NIAID to:

- Understand the attitudes, beliefs, and behaviors of priority populations in order to develop effective communication materials for the target audience;
- Design messages and select material formats (e.g., brochures, posters, radio public service announcements) that may have the greatest potential to influence the target audience's attitudes and behavior to support HIV vaccine research;
- Determine the best promotion and distribution channels to reach the target audience with appropriate messages; and
- Expend limited program resource dollars wisely and effectively by creating materials that best meet the target audience's 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 that is sought requires responses elicited from semi-structured FGs and open-ended questions, rather than from a structured questionnaire.

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

This research addresses communities disproportionately affected by HIV/AIDS and under-represented in HIV vaccine trials and seeks to explore community values relative to HIV vaccine research and to assess the usefulness of materials that can be provided to those communities. Between 2001 and 2003, NIAID conducted research with the same target 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. The FGs will help inform NIAID whether changes in awareness, attitudes, and knowledge have occurred among the populations of interest, and if so, whether these changes necessitate revisions to current messaging and materials. As such, the FG research does not duplicate the previous data collection on this topic, and we are not aware of publications of other research that achieved the same goals that may duplicate this individual collection (see Focus Group Moderator's Guide attached as Appendix 1).

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.

A.6. Consequences of Collecting the Information Less Frequently

Participation will be voluntary and FG respondents will not be re-contacted. FGs are appropriate because they collect a large amount of information from several respondents during one brief discussion.

[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.

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 develop new messages or materials or to revise existing ones. FGs will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

A.8. Consultation Outside the Agency

The 60-day and 30-day Federal Register notices from the generic clearance request (ICRAS: 0925-0585) are attached as Appendix 2. 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 pre-testing 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.

A monetary incentive of, $75.00, is suggested for this recruitment. This rate is requested for the following reasons:

- Eligibility criteria for focus group participants are specific. All FG 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 and 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 participation in 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 make arrangements for child care.

[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.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 gay, lesbian, bi-sexual and transgendered people). NIAID and AED will receive participant first names and demographic characteristics (see Screener attached as Appendix 4). 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 attached as Appendix 6).

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 7).

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 though 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 Screener in Appendix 4) and on the informed consent form (attached as Appendix 6). 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

The estimated time for the annual burden from implementing this research, summarized in Table 12-1 below, is based on 24 focus groups consisting of 9 people each, for a total of 216 people. The length of time for the sessions draws on the research contractor's extensive experience with similar FGs.

Table 12-1. Estimates of Hour Burden

Form Name	Total Number of Respondents	Frequency of Response	Average Time Per Response	Annual Hour Burden
Moderator's Guide: HIV Vaccine Research--Formative Research	216	1	2	432.0

Annualized costs, 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] The cost to individual respondents is approximately $39.12 based on the mean hourly wage of $19.56/hour and an average respondent burden of 2.00 hours per respondent.

Table 12-2. Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Response	Hourly Wage Rate	Average Time Per Response	Respondent Cost
Lay public	216	1	$19.56	2.00	$8,449.92

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.

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 to conduct

[4] U.S. Dept. of Labor, Bureau of Labor Statistics. May 2007 National Occupational Employment and Wage Estimates, United States. Accessed on May 27, 2008 at http://www.bls.gov/oes/current/oes_nat.htm#b11-0000.

this type of research would be approximately $80,000 for each FG study. This estimate included the cost of study design, recruitment, moderator, and data collection. This particular study requests up to 24 FGs be conducted with a total anticipated cost of $140,000 for this information collection. 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 FG study under the existing generic study titled “Pretesting of NIAID’S HIV Vaccine Research Education Initiative Communication Messages” (OMB #0925-0585). This represents the second sub-study, which, once approved, will be indicated by 0925-0585-02.

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 24 FGs. Results for this FG study will be summarized within 2-4 weeks after the completion of the last FG. Thematic analysis will be conducted using standardized practices for qualitative research. Results of selected findings will be used to develop or refine existing 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 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.