

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

Mini Supporting Statement

Video Concept Pretesting

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Table of Contents

Section A. JUSTIFICATION.....	3
A.1. Circumstances Making the Collection of Information Necessary.....	3
A.2. Purposes and Use of the Information.....	4
A.3. Use of Information Technology and Burden Reduction.....	5
A.4. Efforts to Identify Duplication and Use of Similar Information.....	5
A.5. Impact on Small Businesses or Other Small Entities.....	6
A.6. Consequences of Collecting the Information Less Frequently.....	6
A.7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5.....	6
A.8. Consultation Outside the Agency.....	7
A.9. Explanation of any Payment or Gift to Respondents.....	7
A.10. Assurance of Confidentiality Provided to Respondents.....	8
A.11. Justification for Sensitive Questions.....	10
A.12. Estimates of Hour Burden Including Annualized Hourly Costs.....	10
A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers	11
A.14. Estimates of Costs to the Federal Government.....	12
A.15. Explanation for Program Changes or Adjustments.....	12
A.16. Plans for Tabulation and Publication and Project Time Schedule.....	12
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.....	13
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions.....	13
Section B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS.....	14

List of Attachments

- Appendix 1: Online Survey Instrument
- Appendix 2: AED Guidelines for Data Security
- Appendix 3: Notification of Application of Privacy Act
- Appendix 4: IRB Exemption Review

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 250 online surveys (OSs) 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. All participants will respond to the same survey, but will review different video products. See Table 1-1 for a breakdown of respondents.

Table 1-1. Respondent Audiences by Research Method

Audience	Total Online Surveys
African American Men (Heterosexual)	40
African American Women (Heterosexual)	40
Hispanic/Latino Men (Heterosexual)	40
Hispanic/Latina Women (Heterosexual)	40
MSM: African American	30
MSM: Hispanic/Latino	20
MSM: Caucasian	20
MSM: Any race/ethnicity	10
Transgender Individuals (Male-to-Female only)	10
TOTAL	250

The required strategies for increasing individual willingness to support or participate in HIV vaccine research have been identified through earlier interviews and focus groups. These research activities found that priority populations are interested in viewing videos about HIV vaccine research topics. Before incurring the expense of creating videos, NIAID would like to test concepts and approaches for the videos. These OSs are intended to pretest novel video concepts and existing video footage from NHVREI and NHVREI partners to 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 videos for the NIAID HIV Vaccine Research Education Initiative (NHVREI). By conducting OSs with individuals, NIAID will be able to determine which novel video concepts and existing video footage are most appealing and would most effectively increase HIV vaccine research knowledge and awareness. The OSs will allow NIAID to gather feedback about the relevance and credibility of proposed video content from a large number of people in NHVREI's priority audiences (n=250).

These OSs will enable NIAID to:

- Gain feedback about educational novel video concepts intended to influence priority populations' attitudes and behavior to support HIV vaccine research;
- Gain feedback about existing NHVREI and NHVREI partner videos; 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

This phase of research will use online surveys to reduce burden on participants. OSs will allow participants to give feedback about the novel concepts and existing videos at a time convenient for them. A Privacy Impact Assessment of the online system is underway and will be completed prior to launching the survey.

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. Since then, significant events have occurred in vaccine research. In September 2007, the failure of the most advanced HIV vaccine candidate at that time and in September 2009, the modestly effective Thai trial, generated publicity that may have changed public opinion significantly from that which was studied in 2001 and 2003. Several research activities (in-depth interviews with stakeholders (OMB #0925-0585-01), focus groups with NHVREI priority populations (OMB #0925-0585-02 and OMB #0925-0585-04); and intercept interviews with NHVREI priority populations (OMB #0925-0585-04)) are leading to the development of new materials, including posters, brochures, and fact sheets. Findings from these information collections also suggest the need for targeted educational videos. NIAID

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.

would like to pretest novel video concepts and existing video footage with the intended audiences. As NIAID intends to develop new materials, the OS 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 Online Survey Instrument 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 online surveys.

A.6. Consequences of Collecting the Information Less Frequently

Participation will be voluntary and respondents will not be re-contacted. The OS format is appropriate because OSs collect a large amount of information during discrete time periods that allow participants to complete the survey at their leisure. OSs 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 will rely on self-selected participants, 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

educational video concepts. OSs 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 OS 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.

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 \$10.00 is suggested for the OS recruitment. This rate is requested for the following reasons:

- Eligibility criteria for OS participants are specific. All OS 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 OSs 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 25 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 keep data stored securely (see AED Guidelines attached as Appendix 2). A subcontractor familiar with AED's guidelines will be secured to recruit potential participants. Potential participants will be asked for specific demographic information. NIAID and AED will receive participant demographic characteristics (see screening information in the Online Survey Instrument attached as Appendix 1). The subcontractor will have access to participant email addresses that are not connected to the

data. There is no other identifying information collected. NIAID/AED will not have access to this 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 3). 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 information in the Online Survey Instrument attached as Appendix 1).

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 4).

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 Online Survey Instrument in Appendix 1). The instrument explains 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 the OS research is summarized in Table 12-1 below. The estimated time for the annual burden from implementing the OS research is based on 400 individuals screened to complete 250 OSs. The length of time for the sessions draws on the research contractor’s extensive experience with similar OSs.

Table 12-1. Estimates of Hour Burden for Online Surveys

Form Name	Total Number of Respondents	Frequency of Response	Average Time Per Response	Annual Hour Burden
Online Survey Instrument: Part 1- Screening	400	1	5/60 hours	33.33
Online Survey Instrument: Part 2- Research Questions	250	1	20/60 hours	83.33
TOTAL	400			116.66

Annualized costs for OS 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 Online Surveys

Type of Respondents	Hourly Wage Rate	Total Burden Hours	Respondent Cost
Lay public	\$20.32	116.66	\$2,370.53

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 for each OS study would be approximately \$30,000. This estimate included the cost of study design, recruitment, survey hosting, and data collection. This particular study requests up to 250 completed OSs with a total anticipated cost of \$24,000. This research will have a small impact on the total cost of approximately \$1,344,000 that was estimated in the full supporting document.

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.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 fifth sub-study, which, once approved, will be indicated by 0925-0585-05.

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

This information collection will result in quantitative data. Analysis will include frequencies and cross-tabulations. OSs will be conducted within eight weeks after OMB approval. We anticipate that it will take no more than two weeks to complete 250 OSs. Results for the OS study will be summarized within 2-4 weeks after the completion of the last survey. Selected findings will be used to develop or refine HIV vaccine research educational videos.

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

NIAID will display the OMB number and expiration date on the survey instrument.

A.18. Exceptions to Certification for Paperwork Reduction Act

Submissions

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

Section B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

The respondent universe for each pretest will be the universe of individuals for whom the strategy is designed, which is individuals at risk of contracting HIV/AIDS in some or all of the following population groups: Blacks/African Americans, Hispanics/Latinos, men who have sex with men (MSM) of all racial/ethnic groups, and transgender individuals (male to female only). This research will include 250 OSs with all participants responding to the same survey, but reviewing different video products.

B.2. Procedures for the Collection of Information

Data collection will be conducted by a subcontractor to the Academy for Educational Development (AED). The OS vendor will host the survey and use a “panel” of potential participants that meet the survey criteria. The “panel” is comprised of individuals who have opted-in to the survey panel. Once an individual joins the panel, they are assigned a “panel number” which does not include personally identifiable information. Potential participants will receive an invitation to complete the survey electronically. Potential participants receive reminder emails to encourage them to complete surveys.

After following a link from the invitation email, potential participants will first complete screening questions to ensure they meet requirements for the survey. If the participant qualifies, they will be given informed consent information. After they agree with the

terms of the survey/informed consent information, they will be asked to complete the survey. Each OS will take up to 25 minutes, including screening.

Upon completion of all questions, participants will automatically receive their incentive through the panel software.

Data is stored by the OS vendor on a secured database with limited network access. All sensitive file transmissions are secured through encryption. Upon completion of the survey, the vendor will send AED all data in a Microsoft Excel or SPSS file.

B.3. Methods to Maximize Response Rates and Deal with Non-Response

The intent of this pretesting activity is to gather sufficient information to refine video concepts prior to production, not to develop reasonably precise point estimates of the population.

Response rates that provide adequate accuracy and reliability for communication pretests are lower than those necessary for “influential information,” e.g., information that will “have a clear and substantial impact on important public policies or important private sector decisions” as described in OMB and agency Information Quality Guidelines. To keep data collection costs low enough to be an appropriate investment and to receive data in a timely fashion, potential participants are invited to complete surveys and receive reminders to encourage them to complete surveys through emails. It is industry standard to accept a response rate of 50-60 percent for communication pretests. The additional

costs associated with obtaining higher response rates are not justified given how the resulting data will be used.

B.4 Test of Procedures or Methods to Be Undertaken

Data collection instruments are typically constructed using standard items previously used in health message and materials pretests conducted by other NIH Institutes and Centers or other governmental or non-governmental organizations. To estimate the burden for administering the OSs, NHVREI project team members were consulted. The project team members conducted a mock online survey. The burden estimate most closely resembles a maximum average burden, since all screening and interview questions were included.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals consulted in the design of methodologies are listed below. Collection of data will be conducted through a competitively awarded subcontract. The subcontract will have HHS or Federal Government Certification and Accreditation. Responsibility for analyzing data obtained through the OS described above will rest with the Academy for Educational Development (AED). All data collection and analysis will be performed in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements.

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