Supporting Statement A for

EVALUATION OF NIAID'S HIV VACCINE RESEARCH EDUCATION INITIATIVE

HIGHLY IMPACTED POPULATION SURVEY

(NIAID)

April 28, 2010

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Supporting Statement Section A

Table of Contents

LIST OF ATTACHMENTS

SUPPORTING STATEMENT

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). NIAID's activities are authorized under 42 USC 285f, wherein it is stated,

> "The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases."

Developing measures that protect against HIV infection is one of NIAID's highest priorities. Methods in development for the prevention of HIV infection include preventive HIV vaccines, microbicides, and pre-exposure prophylaxis (PrEP). Given the daunting complexity of the HIV virus, developing these methods will ultimately require tens of thousands of volunteers to participate in clinical trials of HIV preventive technologies. In the United States, minority participation in HIV prevention clinical trials is essential; nearly two-thirds of people diagnosed with HIV in the United States are African American or Hispanic/Latino. Historically, recruitment of racial/ethnic populations has been a critical challenge for medical researchers, and initiatives to increase recruitment of these groups into cancer and chronic disease trials have only been partially successful.

To address the need for volunteers in HIV vaccine clinical trials and enable NIAID to fulfill its Congressional mandate to prevent infectious diseases like HIV/AIDS, NIAID created the NIAID HIV Vaccine Research Education Initiative (NHVREI). The goal of NHVREI is to increase knowledge about and support for HIV vaccine research among U.S. populations most heavily affected by HIV/AIDS—in particular, African Americans, Hispanics/Latinos, men who have sex with men (MSM), women, and youth, recognizing the intersection of these groups.

A critical component of NHVREI is outreach to members of these specific highly impacted populations. With the assistance of funded community-based and national organizations, NHVREI is designing, developing, and disseminating HIV vaccine research-related messages to NHVREI target audiences. These messages are delivered through print (e.g., brochures, posters, fact sheets, information kits), radio, TV, and Internet resources. Print materials are distributed through various NHVREI program activities (e.g., trainings, conferences, symposia) and other NIAID-funded partners, governmental and non-governmental organizations.

NIAID is conducting an evaluation of the NHVREI program in order to provide direction for future activities. The evaluation includes: (1) a process evaluation to extract details of how NHVREI is implemented, (2) an outcomes evaluation to investigate the impact of NHVREI, and (3) a population survey to guide future HIV prevention research education activities. On July 16, 2009, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.), NIAID posted the required 60-day Federal Register Notice proposing two collections related to the process and outcomes parts of the evaluation, as part of the process for requesting clearance from the Office of Management and Budget (OMB). These data collections utilizing focus groups and an online survey were approved by OMB in January 2010 (OMB Number 0925-0611) .

With this document, NIAID requests clearance for the third part of the evaluation, a survey of the general population and members of the U.S. populations most heavily impacted by HIV/AIDS. The survey will be conducted once in 2010. The total number of respondent burden hours will not exceed 1,167 annually.

A.2. Purpose and Use of the Information Collection

This survey will gather information about awareness, knowledge, and attitudes supportive of the development of methods to prevent HIV (i.e., vaccine, microbicides, and PrEP) within the general U.S. population as well as populations highly impacted by HIV/AIDS. The survey will also identify negative belief patterns and concerns that undermine support for HIV prevention methods and deter participation in clinical trials.

Because NHVREI is a national program, the survey will utilize established, address-based sampling strategies to obtain nationally representative samples for the general population,

African-Americans, and Hispanic/Latinos. Obtaining a true nationally representative MSM sample is more difficult and costly to achieve because it is a rare population, and for this reason the address-based MSM sample will be augmented by a probability-based, online panel. The sampling plan set forth in Section B. 1 describes a best available sampling strategy that balances NIAID program needs with funding constraints. Estimates associated with the MSM sample in presentations and documents will be accompanied by language explaining its limitations, as discussed in Section B.1.

The major questions to be answered by the survey are targeted at both the general and the highly impacted population. The questions include:

- How salient is the development of new methods for preventing HIV infection, and does salience differ by population?
- What is the level of awareness related to each of the new prevention methods?
- What proportions of the populations of interest agree with positive statements regarding clinical trials for HIV prevention research?
- What proportions of the populations of interest are willing to engage in behaviors that support HIV prevention research?
- Does support for HIV prevention research differ according to the method being developed (i.e., vaccine, microbicides, or PrEP)?
- What concerns create the biggest barriers to support for HIV prevention trials, and do they differ by population and by method?
- Does the willingness to support clinical trials for HIV prevention research change after completion of the survey?

Evaluation data will be used to refine program strategies and messages, so that the effectiveness of the program can be improved. Data will be used internally by NIAID and may be reported to interested professional audiences through presentations and/or published papers as the opportunity arises.

A.3. Use of Information Technology and Burden Reduction

Technological strategies will be used to minimize the burden of data collection for the survey. The initial means of data collection will be through a self-administered, online survey

through the Internet. Potential participants from the Address Based Sample (ABS) (consisting of the general population, African American augment, and Hispanic/Latino augment) will be mailed a letter with a web site address and a password so that they can participate in the survey. Potential MSM augment participants from the Knowledge Networks Panel will be notified of the study and the website via e-mail. The online survey will be designed for ease and convenience.

Online administration of the survey will limit the presentation of questions to those that are relevant to the respondent. In contrast, in paper surveys, respondents are often asked to skip items that are rendered irrelevant by answers to previous questions. For example, on paper, respondents reporting no awareness of HIV prevention methods must skip past questions related to the source of information to answer the next item. Online surveys can move interviewers/respondents directly from a screen showing an awareness question to a screening showing the next relevant item, saving time and increasing the accuracy of data collection.

Online administration of the survey is efficient because the interviewer/respondent enters data directly into the database, avoiding the separate step of key entry of paper survey data into a database. The cleaning of the data is also facilitated by online administration because the survey program software will not permit entering out-of-range answers. If an interviewer/respondent has reservations or comments about the forced choices presented to him/her, the respondent can enter text in a comment box associated with the item at any time.

After several days, nonrespondents to the online survey that are in the ABS sample and that have telephone numbers matched to their addresses will be called and asked to complete the survey by telephone. During the telephone interview, the interviewer will administer questions and record responses through a computer-assisted telephone interview system (CATI).

Respondents without known telephone numbers may set an appointment for a telephone interview by means of a notification card or by leaving a telephone message in response to a mailing. A sophisticated data system that integrates online and telephone receipts with mailings and outgoing calls will ensure that only true non-responders will receive follow-up calls and mailings

A Privacy Impact Assessment (PIA) is being completed for this request.

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

There are no known data sources other than the proposed primary data collection activities that will meet the needs of the NHVREI evaluation. NIAID actively works with other government agencies, including CDC, regarding HIV/AIDS prevention, and NHVREI program staff attend national meetings and are in frequent contact with HIV/AIDS experts across the globe. NIH is the U.S. Government lead for HIV vaccine research, discovery, and development and coordinates with other U.S. Government agencies on HIV vaccine clinical research efforts through the Partnership for AIDS Vaccine Evaluation (PAVE). Through this mechanism, NIAID consults regularly with other agencies to help ensure accuracy and consistency and to avoid duplication of effort. NIAID also regularly consults and coordinates with non-U.S. Government HIV vaccine research organizations through formal and informal channels.

Little information is available regarding attitudes toward HIV prevention methods in the United States. Information about attitudes toward vaccine research in the United States general and highly impacted populations was collected in 2002,[1] but that study did not create national estimates. The present survey expands on the 2002 study by (1) creating national estimates, (2) using better methods for obtaining representative samples, and (3) expanding the target of data collection beyond vaccines to other prevention methods (i.e., microbicides and PrEP). It is also highly possible that attitudes toward the development of HIV prevention methods have shifted in unexpected ways in light of the economic downturn, changes in the research landscapes, and the targeted education activities implemented since 2002.

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

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection scheduled to start as soon as possible after OMB clearance in early 2010. The timing of the data collection is essential to inform NIAID's ongoing

1 Allen MA, Liang TS, La Salvia T, Tjugum B, Gulakowski RJ, Murguía M. Assessing the attitudes, knowledge, and awareness of HIV vaccine research among adults in the United States. ***J Acquir Immune Defic Syndr.*** **2005 Dec 15;40(5):617-24.**

educational initiatives and the design of follow-on activities. NIAID plans to launch a follow-on HIV prevention research education activity during FY2011 and intends to incorporate lessons learned from the NHVREI evaluation into the design of the subsequent programs.

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

This information collection fully complies with 5 CFR 1320.5(d) (2).

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The required 60-day notice appeared in the Federal Register on August 31, 2009 (Volume 74, Number 167, p. 44855-44856), soliciting comments on the requested new data collection project. Two public comments were received. One stated that the research was unnecessary because there has already been a lot of HIV/AIDS research and people should know how to protect themselves from HIV. Given that this survey will look at knowledge, attitudes, and behaviors in a new HIV vaccine research environment, it is important to capture this information to assist NIH for future HIV vaccine efforts. In another response a person working for an organization receiving funding through the NHVREI project expressed support for the effort and offered to provide assistance with the survey.

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 were consulted to review the plans contained herein for program development research and evaluation of NIAID educational initiatives, and their comments and suggestions have been incorporated into these data collection plans.

Those outside NIAID who have been consulted about this study include:

- Sarah Alexander, HIV Vaccine Trials Network, 206-667-5296, salex@hvtn.org
- Cornelius Baker, Academy for Educational Development, 202-884-8612, cbaker@aed.org
- Bonny Bloodgood, Academy for Educational Development, 202-884-8727, BBloodgood@aed.org
- Russell Brewer, Academy for Educational Development, 202-884-8797, rbrewer@aed.org

- Gail Broder, HIV Vaccine Trials Network, 206-667-7348, gbroder@fhcrc.org
- Larry Bye, Field Research Corporation, 415-392-5763, larryb@field.com
- Stacy Carrington-Lawrence, NIH/OD, 301-435-8930, carringtons@od.nih.gov
- Charles DiSogra, Knowledge Networks, 650-289-2185, cdisogra@knowledgenetworks.com
- Dan Eckstein, NOVA Research Company, 301-986-1891, deckstein@novaresearch.com
- Mansour Fahimi, Marketing Systems Group, 800-336-7674, mfahimi@m-s-g.com
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- Diane Johnson, Kelly Services, 301-451-8715, johnsondr@mail.nih.gov
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- Marta Leon-Monzon, NIH/OD, 301-496-4564, LEONM@od31em1.od.nih.gov
- Elyse Levine, Academy for Educational Development, 202-884-8727, elevine@aed.org
- Stacey Little, Academy for Educational Development, 202-884-8727, slittle@aed.org
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- Wendy Wertheimer, NIH/OD, 301-496-0357, WERTHEIW@od31em1.od.nih.gov
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- Fulvia Veronese, 301-402-4148, fv10x@nih.gov
- Kevin Wright, 301-402-3574, wrightk@mail.nih.gov

Consultation with representatives of those from whom information will be obtained occurred through cognitive interviews conducted in July and August 2009.

A.9. Explanation of Any Payment of Gift to Respondents

Tokens of appreciation are commonly used in order to obtain assistance from those who may not otherwise participate in data collection efforts. There is extensive literature to support the use of incentives, particularly monetary incentives, as a supplement or complement to other efforts of persuasion to ensure recruitment of a representative sample. Rather than relying on potential respondents' interest in the topic of the survey or a sense of civic obligation, researchers provide incentives to stimulate cooperation across people with different backgrounds and interests.[2] Incentives are particularly important for disenfranchised, hard-to-reach and minority populations, especially with survey topics that may seem insignificant to the potential respondent. 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.[2,3]

2 Singer, E., *The use of incentives to reduce nonresponse in household surveys*, in *Survey Nonresponse*, R.M. Groves, et al., Editors. 2002, Wiley and Sons: New York. p. 163-178. Available at http://www.isr.umich.edu/src/smp/Electronic Copies/51-Draft106.pdf. Accessed On April 15, 2009.

3 Singer, E. and K. R.A., *Paying respondents for survey participation*, in *Studies of Welfare Populations: Data Collection and Research Issues*, M. Ver Ploeg, et al., Editors. 2002, National Academy Press: Washington, DC.Available at http://aspe.hhs.gov/hsp/welf-res-data-issues02/04/04.htm. Accessed on April 15, 2009.

The use of modest prepayments to improve response rates is well-established in mail surveys[4,5] and is in widespread use for large telephone surveys. There are several ongoing large telephone surveys that tested experimentally and have subsequently implemented advance letters with prepayments of $2-$5 after positive results. These surveys include: the National Household Education Survey from the U.S. Department of Education; the California Health Interview Study, supported in part by the National Cancer Institute (NCI); the National Survey on Children's Health from the Health Resources and Services Administration; the Health Information National Trends Survey from NCI; the National Survey of Adults and Families from the Urban Institute; and the Health Tracking Household Survey from the Center for Studying Health System Change. Because much of nonresponse in telephone surveys is due to an inability to make initial contact, the presentation of cash with the advance letter serves to incentivize an important first step by making the advance letter and its content more memorable. It is a novel and unexpected gesture that brings additional attention to the mailing, and as a goodwill gesture it brings in respondents who may not otherwise respond.[6] Finally, though the effects of prepaid incentives within advance letters for web-based surveys have not been widely evaluated, initial findings appear promising.[7]

Based on the extensive literature on survey prepayment, and because obtaining opinions from minorities is critical to the success of the survey, the use of a $2 prospective incentive is recommended for respondents from the ABS samples (i.e., the general population, African American Augment, and the Hispanic/Latino augment).

Many potential respondents are likely to have minimal awareness of the survey topic, so the incentive is necessary to arouse interest and attention. Furthermore, because people have

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4 Church, A.H., Incentives in mail surveys: A meta-analysis. *Public Opinion Quarterly*, 1993. **57**: p. 62-79.

5 Larson, P., Chow, G. Total cost/response rate trade-offs in mail survey research: Impact of follow-up mailings and monetary incentives. *Industrial Marketing Management* 2003;32:533-7.

6 Dillman, D.A., *Internet, Mail, and Mixed Mode Surveys: The Tailored Design Approach*. Third ed. 2009, Hoboken, NJ: John Wiley and Sons.

7 Tourkin, S., et al., (Inter) net gain? Experiments to increase web based response in *American Association For Public Opinion Association*. 2005: Fontainebleau Resort, Miami Beach, FL.<Not Available>. 2009-05-25 from http://www.allacademic.com/meta/p16793_index.html

multiple demands on their time, completing the survey is likely to fall to the bottom of their priority list unless there is some incentive involved.

After the main data collection process is complete, a mailing to a random sample of nonresponders in the ABS will be sent, with $2 cash in the mailing envelope. We expect that obtaining responses from nonresponders after the considerable follow-up effort will be difficult, even though the number of questions is short and the questions are not sensitive.

Respondents from the established online panel that comprise the MSM augment sample will be provided with compensation in accordance with Knowledge Networks policy after completion of the survey. KnowledgePanel members who use their own personal computers to access the Internet and take KN surveys receive 1,000 points for each completed survey, and if the survey exceeds 25 minutes an extra 5,000 bonus points. Points are redeemable as cash with 1,000 points equivalent to $1.00. When a panel member's account accumulates 25,000 points they are sent a check for $25.00. Panel members who have been provided a laptop computer and free Internet access from Knowledge Networks receive only bonus points as appropriate and not the 1,000 points per survey. These members recognize the computer and free Internet as their compensation.

A.10. Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept private to the extent permitted by law. This will be communicated to respondents by means of introductory letters and explanatory texts on the cover pages of questionnaires. NIAID and its contractors will follow best practices to maximize privacy and security of all data.

For the survey, each respondent will be assigned a unique identification (ID) number. This number will be used as a unique record identifier for survey answers. The data file containing names and ID numbers will be maintained separately from the file containing survey answers. Both files will be maintained in a secure environment. Contact information will be used by the subcontractor only for mailing a letter requesting subject participation and for subsequent followup in the case of non-response.

Instructions on the survey will apprise the respondent of the following:

- The survey is sponsored by the National Institute on Allergy and Infectious Diseases, part of the National Institutes of Health.
- Survey data will be used to help NIAID develop educational programs on research to prevent the spread of HIV.
- Respondents will not be identified in any reports or publications.
- Answers will be assigned a confidential ID instead of a name.
- Survey answers and respondent mailing information will be stored according to best practices for data security.
- Name and mailing information will be deleted at the end of the data collection period.
- All respondent answers will be combined and analyzed as a group.
- For survey respondents, providing the information is voluntary, and there are no penalties for not responding to the information collection as a whole or to any particular questions.

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, and in the **Federal Register** published on Friday, January 20, 1995 (Vol. 60, No. 13 p. 4277). A statement from the Privacy Act Officer at the NIH is found in Attachment A.

The Institutional Review Boards working with the two contractors have reviewed and approved the study. Approval documentation may be found in Attachment B.

A copy of the survey can be found in Attachment C. The letters, follow-up scripts, and e-mail templates may be found in Attachment D.

A.11. Justification for Sensitive Questions

There are two topics of a sensitive nature. The first topic is related to HIV status. The first is necessary because HIV-positive individuals are likely to have strong opinions about HIV/AIDS prevention but are not eligible to participate in HIV prevention trials. There is concern that if unidentified, the answers of persons with HIV might skew estimates, particularly in highly impacted populations. The second topic is related to sexual orientation and behavior. Because men who have sex with men (MSM) are one of the highly impacted populations targeted by NHVREI now and in the future, it is critical to identify the responses of these

individuals. Procedures are in place to safeguard the identity of individuals who provide us sensitive information, as described in section A10.

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

Response burden estimates are shown in Table A.12-1. The survey questionnaires will require 20 minutes to complete. The target number of survey respondents is 3,250 individuals. Table A.12-1 shows the average burden hour per survey respondent is 0.33333, with the estimated total annual burden hours estimated at 1,073. This estimate is based on experience with the cognitive interviews described in Section B.4.

Table A.12 – 1 Estimates of Hour Burden

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
General Population	3,250	1	0.33333	1,073
Totals	3,250	1	0.33333	1,073

The total annualized cost to respondents is estimated at $22,013 as shown in Table A.12-2. Annualized costs use the mean hourly wage for all occupations of $20.32, provided by the U.S. Department of Labor, Bureau of Labor Statistics (the latest data available).

A.12 – 2 Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Response	Average Time Per Respondents	Hourly Wage Rate	Respondent Cost
General Population	3,250	1	0.33333	$20.32	$22,013
Totals	3,250	1	0.33333	$20.32	$22,013

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

There are no capital or start-up costs to the data collection efforts requested; nor are there any costs associated with operation, maintenance, or purchase of services.

A.14. Annualized Cost to the Federal Government

The annualized cost to the government to conduct and analyze the survey is $336,666 per year over the 3 years of the project. The budget includes the costs of survey design and development, all data collection and followup, incentive payments, data file preparation and documentation, initial analyses, and other miscellaneous costs such as supplies, expenses, and postage. Professional service time is included for study management and overhead costs.

A.14 – 1 Estimates of Annualized Cost to the Government	
Year	**Estimated Costs**
2009	100,000
2010	890,000
2011	20,000
Total Over Three Years	**1,010,000**

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

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

The current plan is to begin the survey data collection in May 2010, if OMB clearance has been received by that date. Otherwise, the survey will be fielded as soon as possible after clearance has been received.

Table 1.16 – 1 Project Time Schedule – Highly Impacted Populations Survey	
Activity	**Estimated Time Schedule**
Start sample draw	Less than one month following OMB approval
Initial mailout recruitment letters	Less than one month following OMB approval
Data collection completed	5 months following OMB approval
Delivery of data file	7 months following OMB approval
Analysis of data	8-9 months following OMB approval
Preliminary Report	10 months following OMB approval
Final Report	12 months following OMB approval

Publication Plan

NIAID anticipates making evaluation results available to a variety of health program planners at government agencies, community-based organizations, health professional organizations, and medical institutions. Findings may also be disseminated through peer-reviewed journals and professional conferences.

Analysis Plan-Survey

This survey will obtain data on respondents' knowledge, attitudes, and behaviors related to support for developing HIV prevention methods.

Key analyses include the following:

(1) Descriptive statistics of variables of interest (i.e., awareness, attitudes, supportive behaviors) by population.

(2) Comparisons of selected variables (e.g., attitudes related to specific prevention measures) by prevention method (i.e., vaccine, microbicide, or PrEP) and by population.

(3) Correlates of support for HIV prevention methods by population and prevention method.

(5) Nonresponse bias analysis.

In the following sections we provide greater detail on these analyses, including examples of table shells.

Descriptive Statistics. Table A.16-2 indicates examples of descriptive data that could provide important programmatic guidance to NIAID on their outreach efforts to the impacted communities. For example, the survey will provide information on the awareness of new HIV prevention methods, existing level of support for HIV prevention research, and concerns regarding participation in clinical trials. The 2002 survey suggested that attitudes and concerns differ by population, and the current survey will look to identify similar findings.

Table A.16 – 2 Reported Awareness and Attitudes Regarding Development of HIV Prevention Methods – Estimates by Populations of Interest				
	Percent of Population Reporting			
	General Population	African American	Hispanic/ Latino	MSM
Relevance of HIV prevention methods				
Agrees that new methods of HIV prevention are needed.				
Fairly or very much concerned about HIV risk for family or friends.				
Perceives development of vaccine, microbicides, or PrEP as fairly or very urgent.				
Awareness of HIV prevention methods				
Read or heard about an HIV vaccine, microbicides, or PrEP within the last year.				
Attitudes regarding HIV prevention				
Agrees that effective HIV vaccine is being kept a secret.				
Fairly or very likely to encourage consideration of participating in clinical trial for any prevention method.				
Reports side effects deter them “a lot” from encouraging others to consider participating in clinical trial.				
Agrees not enough knowledge to encourage others to participate in clinical trials.				

Comparisons of Prevention Methods. Comparisons will be made between the attitudes and knowledge related to each of the different prevention methods. Table A.16-3 shows how findings could be displayed. These analyses will also be conducted within populations of interest to examine whether they differ in important ways. Chi-square analyses will be used to examine differences among samples.

Table A.16- 3 Comparisons of Awareness and Attitudes by Prevention Methods			
Awareness, Attitudes, and Behaviors Measured for each HIV Prevention Method	**HIV Prevention Method**		
	Prevention Vaccine	**Microbicides**	**PrEP**
Read or heard about it.			
Fairly or very urgent to develop.			
Agrees that more information is needed before considering participation in clinical trial.			
Concern about side effects deters from encouraging others to participate in clinical trial "a lot."			
Fairly or very likely to use.			
Fairly or very likely to encourage friend or family member to participate in clinical trial (body of survey).			
Fairly or very likely to encourage friend or family member to participate in clinical trial (at end of survey).			

Correlates of Support for HIV Prevention Methods. Composite scores indicating high versus low levels of support will be constructed based on observed distributions in the entire sample. Respondents reporting high levels of support will be compared with those with low levels of support on number of different variables, including race/ethnicity, sexual orientation, education, income, saliency of HIV/AIDS, awareness of prevention methods, likelihood of using prevention methods, and attitudes/beliefs. Logistic and linear regression modeling will help identify correlates of support. Regression analysis within each population group will be conducted. Chi-square analyses will be used to explore relationships.

Non-Response Bias Analysis. As described in Section B.3, considerable effort will be expended to minimize rates of nonresponse. Data will be weighted for nonresponse, as described in B.2. Analyses will be conducted on the characteristics of individuals who do not respond to the survey based on information obtained from a brief survey sent to a random sample of nonresponders and on available geographic information. Included in the nonresponse survey are

demographic questions and a question "Has someone close to you been infected with HIV/AIDS?" The latter is included because it is likely to be predictive of attitudes regarding HIV prevention but is short, easily replied to, and not overly sensitive. An analysis of early and late responders will provide additional information about persons who are reluctant to respond.

Typically, surveys that secure a response rate less than 80 percent are expected to conduct a nonresponse bias analysis to assess the potential magnitude of nonresponse bias before the data or any analysis using the data are released. For this purpose, estimates of survey characteristics for nonrespondents and respondents are required to assess the potential nonresponse bias.

The bias in an estimated mean based on respondents, $\bar{y}_R$, is the difference between this estimate and the target parameter, μ, which is the mean that would result if a complete census of the target population was conducted and all units responded. This bias can be expressed as follows:

$$B(\bar{y}_R) = \bar{y}_R - \mu$$

However, for variables that are available from the frame, μ can be estimated by $\hat{\mu}$ without any sampling error, in which case, the bias in $\bar{y}_R$ can then be estimated by:

$$\hat{B}(\bar{y}_R) = \bar{y}_R - \hat{\mu}$$

Moreover, an estimate of the population mean based on respondents and nonrespondents can be obtained by:

$$\hat{\mu} = (1 - \hat{\eta})\,\bar{y}_R + \hat{\eta}\,\bar{y}_{NR}$$

where $\hat{\eta}$ is the weighted unit nonresponse rate, based on weights prior to nonresponse adjustment. Consequently, the bias in $\bar{y}_R$ can be estimated by:

$$\hat{B}(\bar{y}_R) = \hat{\eta}(\bar{y}_R - \bar{y}_{NR})$$

That is, the estimate of the nonresponse bias is the difference between the mean for respondents and nonrespondents multiplied by the weighted nonresponse rate, using the design weight prior to nonresponse adjustment. Here, a respondent will be defined as any sample

member who is determined to be eligible for the study and has valid data for the selected set of key analytical variables.

The steps for nonresponse bias analysis include estimating the nonresponse bias and testing (after adjusting for multiple comparisons) to determine whether the bias is significant at the 5 percent level. In the second step, our nonresponse adjustments procedure will be designed to significantly reduce or eliminate nonresponse bias based on the information obtained during the first step. In the third step and after the nonresponse-adjusted weights have been computed, any remaining bias for key variables will be estimated, and statistical tests will be performed to determine the significance of any remaining nonresponse bias. It should be noted that results from these steps will also guide the final step of weight calculations where weighted totals will be forced to match reported totals across dimensions for which survey data and corresponding population estimates are available.

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

NIAID will display the OMB control number and expiration date in the upper right-hand corner of all data collection instruments. We are not seeking a waiver to display the expiration date for OMB approval.

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

NIAID is in full compliance with the provisions contained within the Certification for Paperwork Reduction Act Submissions.