Supporting Statement A for

EVALUATION OF NIAID'S HIV VACCINE RESEARCH EDUCATION INITIATIVE

HIGHLY IMPACTED POPULATION SURVEY

(NIAID)

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Supporting Statement Section A

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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 assess its impact and generate key findings applicable toward the design of future educational initiatives. 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 are currently under review.

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 provide population estimates for the general and highly impacted populations (African American, Hispanic/Latino, and MSM) regarding the proportion of U.S. individuals reporting awareness, knowledge, and attitudes supportive of the development of methods to prevent HIV (i.e., vaccine, microbicides, and PrEP). In addition, the survey will identify concerns that deter participation in clinical trials as well as other negative attitude patterns that can be targeted by future educational efforts. Information obtained will be used to

guide future programs designed to improve support for the development of HIV prevention measures.

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 primary means of data collection will be through a Computer-Assisted Telephone Interview (CATI), with the telephone interviewer administering questions and recording responses through a computer-assisted survey instrument. As a secondary choice, participants may self-administer a similar, online survey through the Internet. Potential participants from the Address Based Sample (ABS) will be mailed a prenotification card with a web site address and a password so that they can participate in the survey. Potential Panel participants (from the

Knowledge Network or Survey Sampling International) will be notified of the study and the website via e-mail. The online survey will be designed for ease and convenience. Respondents that prefer providing information by telephone can set an appointment for a telephone interview by means of a notification card or by leaving a telephone message. 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, mailings, and e-mails, and that a $20 incentive will be sent within one week of survey completion.

Online administration 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.

A Privacy Impact Assessment (PIA) has not been completed for this request. The IT system has not yet been developed. We will work with the NIH Privacy Officer to arrange to have a Privacy Impact Assessment conducted prior to implementation of the system.

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 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).

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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.**

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
- Stacy Carrington-Lawrence, NIH/OD, 301-435-8930, carringtons@od.nih.gov
- Dan Eckstein, NOVA Research Company, 301-986-1891, deckstein@novaresearch.com
- Andrew Forsyth, NIH/NIMH, 301-443-8403, aforsyth@mail.nih.gov
- Lisbeth Jarama, NOVA Research Company, 301-986-1891, LJarama@novaresearch.com
- Diane Johnson, Kelly Services, 301-451-8715, johnsondr@mail.nih.gov

- Catharine Laube, Henry M. Jackson Foundation, 301-451-2795, laubec@niaid.nih.gov
- 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
- Bonnie Mathieson, NIH/OD, 301-496-4564, MathiesB@od31em1.od.nih.gov
- Caroline McLeod, NOVA Research Company, 301-986-1891, CMcLeod@novaresearch.com
- Enid Moore, HIV Vaccine Trials Network, esmoore@fhcrc.org, 206-667-4721
- Kaijson Nolimar, HIV Vaccine Trials Network, 206-667-7481, kaijson@kaijson.com
- Sandra Sitar, Kelly Services, 301-594-8569, sitars@mail.nih.gov
- Steven Wakefield, HIV Vaccine Trials Network, 206-667-6705, wakefield@hvtn.org
- Wendy Wertheimer, NIH/OD, 301-496-0357, WERTHEIW@od31em1.od.nih.gov
- Paul Young, NOVA Research Company, 301-986-1891, PAYoung@novaresearch.com
- Allison Zambon, NOVA Research Company, 301-986-1891, azambon@novaresearch.com

NIAID staff who have been consulted about this study include:

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- Kathy Stover, 301-451-2278, stoverk@niaid.nih.gov
- Brandie Taylor, 301-451-3068, taylorbr@niaid.nih.gov
- 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, primarily monetary incentives, as a supplement or complement to other efforts of persuasion to ensure recruitment of a representative sample. Incentives are particularly important for hard-to-reach and minority populations or 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]

Because the topic of HIV prevention research is not a familiar or attractive topic and because obtaining opinions from minorities is critical to the success of the survey, the use of a $20 incentive is recommended for respondents from the ABS frame (i.e., the General Population, African American Augment, and the Hispanic/Latino Augment).

Respondents involved in the established online panels (who will represent an augment sample of MSM) will be provided with a $5 incentive in addition to a general compensation provided in accordance with the policies of the companies that have established these panels. The general incentives, combined with a $5 study-specific incentive, will make respondent incentives comparable to the $20 that the ABS respondents will receive. 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 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.

During the nonresponse analysis mailing to a sample of nonresponders, all potential respondents will receive $2 cash in the mailing envelope. It is well established that a small, non-

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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://aspe.hhs.gov/hsp/welf-res-data-issues02/04/04.htm. Accessed on April 15, 2009.

3 Singer E. The use of incentives to reduce nonresponse in household surveys. The University of Michigan Institute for Social Research Survey Research Center. Available at http://www.isr.umich.edu/src/smp/Electronic Copies/51-Draft106.pdf. Accessed On April 15, 2009.

contingent incentive is an effective method for increasing response rate, particularly when the field period is short.[4] 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. Therefore, the incentive is set at $2 rather than $1.

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.

4 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.

- 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 questions of a sensitive nature. The first question is related to HIV status. This question 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 question is related to sexual orientation. 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 3,500 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 1,167. 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	3500	1	0.33333	1,167
Totals	3500	1	0.33333	1,167

The total annualized cost to respondents is estimated at $23,706 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	3,500	1	0.33333	$20.32	$23,706
Totals	3,500	1	0.33333	$20.32	$23,706

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 February 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 pre-notification cards	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 the nonresponse analysis mailing and on available geographic information.

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.