

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Evaluation of the NIAID HIV Vaccine Research Education Initiative

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 16, 2009, pages 53259–53260 and allowed 60 days for public comment. Three public comments were received and responses were sent to each person. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection:* Title: Evaluation of the NIAID HIV Vaccine Research Education Initiative Highly Impacted Population Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Developing

measures that protect against HIV infection is one of NIAID’s highest priorities. Methods in development for the prevention of HIV infection include 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 HIV preventive clinical trials. In the United States, minority participation in clinical trials of HIV prevention technologies 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. Part of the evaluation includes a population survey to guide future NHVREI activities.

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. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* General U.S. population with oversampling of subpopulations highly impacted by HIV. The annual reporting burden is shown in the table below. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

	Total # of respondents	Hours per response	Total hours
Highly Impacted Population Surveys .....	3,500	0.33333	1,167

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology.

*For Further Information:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov), or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Katharine Kripke, Assistant Director, Vaccine Research Program, Division of AIDS, NIAID, NIH, 6700B Rockledge Dr., Bethesda, MD 20892–7628, or call non-toll-free number 301–402–0846, or

e-mail your request, including your address to [NIAIDSurvey@NIH.gov](mailto:NIAIDSurvey@NIH.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

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