

DATE: October 29, 2008

TO: Office of Management and Budget

THRU: Project Clearance Officer, DHHS  
Project Clearance Officer, NIH  
Project Clearance Liaison, NIAID

FROM: Katharine Kripke, Assistant Director  
National Institute of Allergy and Infectious Disease  
Division of AIDS  
Vaccine Research Program

SUBJ: Pretesting of NIAID's HIV Vaccine Research Education Initiative  
(OMB No. 0925-0585; Expiration Date 2/28/11)

In accordance with the terms of the generic clearance granted by OMB to the Division of AIDS, NIAID on February 28, 2008, I have electronically attached the submission for the second individual collection requested under this generic clearance (tracking # 0925-0585-02). This collection includes focus groups with individuals from four US populations highly affected by HIV/AIDS.

The National Institute of Allergy and Infectious Diseases' (NIAID) Division of AIDS funds HIV vaccine research. In an effort to develop support for HIV vaccine research, NIAID has created the NIAID HIV Vaccine Research Education Initiative (NHVREI) to educate US populations most affected by HIV about vaccine research. As part of NHVREI, local and national non-governmental partner organizations have committed to share information and educational materials about HIV vaccine research. NIAID developed educational materials in 2006 to meet this need; however, major events in vaccine research have occurred since then. NIAID does not know the extent to which these materials remain effective with the target audiences. As a result, NIAID plans to conduct formative research with African Americans, Hispanics, men from all racial and ethnic groups who have sex with men (MSM), and transgender individuals (male to female only). This formative research includes a total of 24 groups across four geographically dispersed U.S. cities, that will gather information about existing HIV vaccine research knowledge, attitudes, and behaviors. In addition to gathering this information, NIAID also plans to ask respondents: what questions they have about HIV vaccine research; what would encourage them to be more supportive of these efforts; and what type of materials they would find useful for increasing knowledge of and support for HIV vaccine research.

African Americans, Hispanics, MSM, and transgender populations will be recruited. These individuals will represent the general population in terms of age, income, and education. NIAID aims to recruit 12 participants for each group to seat nine, for a total of 216 respondents participating in the focus groups. Thus, the total respondent burden for this effort is 432.0 hours (the sum of two hours for approximately 216 non-government employee respondents). This effort will account for 11.7 percent of the total annual burden hours (3689.0) granted in our approval package.

This submission includes:

- o Supporting statement;
- o Generic clearance form;
- o OMB burden statement;
- o Screener document;
- o Moderator's guide;

- o Informed consent document; and
- o IRB exemption review.

Please feel free to contact me if you have any questions.

Katharine Kripke, Ph.D.