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TO: Office of Management and Budget

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

FROM: Katharine Kripke, Assistant Director
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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 fourth individual information collection requested under this generic clearance (tracking # 0925-0585-04). This collection includes focus groups and intercept interviews with individuals from four US populations highly affected by HIV/AIDS.

NIAID funds HIV vaccine research. In an effort to develop support for HIV vaccine research, NIAID created the NIAID HIV Vaccine Research Education Initiative (NHVREI) to educate US populations most affected by HIV/AIDS about HIV vaccine research. In 2006, NIAID developed educational materials about HIV vaccine research; however, major events in HIV vaccine research have since occurred, creating a need to reexamine the messages and materials to ensure they remain appropriate for the current environment. Based on the outcome of pretesting with target audiences (OMB-cleared instruments: "In-Depth Interviews for Message and Materials Pretesting" and "Focus Groups for Message and Materials Pretesting") NIAID developed new educational materials for subsequent rounds of pretesting. This pretesting will include a series of focus groups (FGs) and intercept interviews (IIs) 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 affected by HIV/AIDS. The results of the FGs and IIs will provide NIAID with guidance for improving its education initiative that aims to increase awareness of and support for HIV vaccine research.

African American, Hispanic/Latino, MSM, and transgender populations will be recruited. These individuals will represent the general population in terms of age, income, and education. For focus groups, NIAID aims to recruit 11 participants for each group to seat nine, for a total of 63 respondents participating in the focus groups. For intercept interviews, NIAID aims to complete 250 intercept interviews. The total respondent burden for this effort is 220.0 hours. A total of 3,248 burden hours have been approved for three years, translating to 1082.66 burden hours per year. This effort will account for 20.3 percent of the total annual burden hours. .

This submission includes:

- o Supporting statement;
- o Generic clearance form;
- o OMB burden statement;
- o Screener document;

- o Moderator's guide;
- o Focus group informed consent document;
- o Intercept interview informed consent document, and
- o IRB exemption review.

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

Katharine Kripke, Ph.D.