

Anticipated 2004–2007 projects	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
(2) Behavioral Risk Factor Surveillance System Survey (BRFSS)	50	1	1.25
(3) Healthy People 2010 (HP 2010)	50	1	1.25
(4) National Survey of Family Growth (NSFG)	50	1	1.25
(5) Pregnancy Risk Assessment Monitoring System (PRAMS)	50	1	1.25
(6) National Health and Nutrition Examination Survey (NHANES)	50	1	1.25
(7) Other questionnaire testing:			
2004	100	1	1.25
2005	100	1	1.25
2006	100	1	1.25
(8) Perceptions of Quality of Life project	80	1	1.25
(9) Perceptions of Confidentiality Project	50	1	1.25
(10) Perception of Statistical Maps Project	50	1	1.25
(11) General Methodological Research	100	1	1.25
Pilot Household Interviews:			
2004 NHIS Modules	50	1	1.25
2005 NHIS Modules	50	1	1.25
2006 NHIS Modules	50	1	1.25
Focus Groups (10 groups of 10 for three years)	300	1	1.50

Dated: December 8, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control And Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Topical Microbicides To Reduce Sexual Transmission of Human Immunodeficiency Virus (HIV)

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS).

ACTION: Opportunities for collaboration for evaluation of topical microbicides.

The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP-SE), Epidemiology Branch (EpiBr), announces an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides designed for vaginal and/or rectal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in women and men.

SUMMARY: The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP-SE) of the National Center of HIV, STD, and TB

Prevention (NCHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (DHHS) seeks one or more pharmaceutical, biotechnical, or other companies that hold a proprietary position on agents which may be useful as microbicides to prevent sexual transmission of HIV infection. The selected company and CDC will execute an Agreement under which the company will provide a product for CDC to study the product's safety and preliminary efficacy as a topical microbicide. Initial studies will include in-vitro assays and may include macaque studies. Agents will be selected for phase I and phase II trials in women and men based upon data obtained in the CDC studies as well as other available published and unpublished safety and efficacy data. Each collaboration would have an expected duration of one (1) to five (5) years. The goals of the collaboration include the timely development of data to further the identification and commercialization of effective topical microbicides and the rapid publication of research findings to increase the number of HIV prevention technologies proven effective and available for use.

Confidential proposals, preferably 10 pages or less (excluding appendices), are solicited from companies with patented or licensed agents which have undergone sufficient preclinical testing to be prepared to submit an Investigational New Drug (IND) application to the FDA within six months of submitting the proposal.

DATES: This Notice will be open indefinitely.

ADDRESSES: Formal proposals should be submitted to Carmen Villar,

Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–5259, (office) 404–639–6130; Fax: 404–639–6127; e-mail: CVillar@cdc.gov. Scientific questions should be addressed to Lisa A. Grohskopf, MD, MPH, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6116, (office) 404–639–6146; Fax: 404–639–6127; e-mail: lkg6@cdc.gov. Inquiries directed to “Agreement” documents related to participation in this opportunity should be addressed to Thomas E. O’Toole, MPH, Deputy Director, Technology Transfer Office, CDC, 1600 Clifton Road, Mailstop K–79, Atlanta, GA 30333; Phone: (direct) 770–488–8611, (office) 770–488–8607; Fax: 770–488–8615; e-mail: TEO1@cdc.gov.

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch (EpiBr) of DHAP-SE/NCHSTP is to develop and evaluate biomedical interventions to reduce HIV transmission. To this end, the EpiBr is establishing contracts to conduct phase I and phase II trials of topical microbicides. EpiBr also funds research in the Division of AIDS, STD, and TB Laboratory Research (DASTLR) of the National Center for Infectious Diseases (NCID) at CDC and with external laboratories to conduct macaque studies and in-vitro studies in support of human microbicide trials. The goal of these efforts is to provide scientific and technical expertise and key resources