

d. The extent to which plans for representation at the annual meeting of awardees reflect the intent to actively collaborate with other awardees through this meeting.

3. Plan of Operation (45 Points)

a. The extent to which the application provides evidence that key personnel have the ability and program skills to develop and carry out the proposed activities;

b. The extent to which the applicant and malaria-endemic partners have demonstrated a collaborative review of the priority needs for malaria in the malaria-endemic country;

c. The extent to which the applicant clearly defines objectives and justifies these objectives in relation to the proposed focus of the plan to address priority issues for the malaria-endemic country RBM program;

d. The adequacy of the plan to carry out major project components (e.g., in both the applicant and malaria-endemic country: leadership, staffing, administrative coordination, planning, and measurement activities), including a timetable that provides major milestones for implementing activities;

e. The degree to which the plan is consistent with malaria prevention best practices and RBM principles;

f. If capacity building for public health in malaria is proposed, the extent to which the planned activities relate to capacity improvements that will benefit RBM activities in the partner country;

g. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

4. Evaluation Plan (15 Points)

The extent to which (a) the applicant describes a detailed plan for monitoring the implementation of the activities and evaluating the extent to which the proposed activities strengthen local and national capacity for malaria prevention and control, and (b) the monitoring and evaluation plan builds on existing

monitoring and evaluation systems in the project area and can demonstrate progress towards RBM objectives.

5. Budget (Not Scored)

The extent to which the budget is detailed, clear, justified, describes in-kind or other project support, and is consistent with the proposed program activities.

6. Human Subjects (Not Scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects? (Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.)

H. Other Requirements

Technical Reporting Requirements Provide CDC with original plus two copies of—

1. annual progress reports;
2. financial Status Report (FSR), no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement in the application kit.

- AR-1 Hunman Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 307, and 317(k)(2) of the Public Health Service Act, [42 U.S.C. sections 241(a), 2421, and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements."

To obtain business management technical assistance, contact: Merlin Williams, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone: 770-488-2765, Email address: mqw6@cdc.gov.

For program technical assistance, contact: Richard W. Stekete, MD, MPH or Craig Leutzinger, Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333, Telephone: 770-488-7760, Fax: 770-488-7761, Email address: ris1@cdc.gov or cll1@cdc.gov.

Dated: June 22, 2001.

John L. Williams,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
(CDC).*

[FR Doc. 01-16248 Filed 6-27-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Disease Control and Prevention

Program Announcement Number 01163 Correction

AGENCY: Centers for Disease Control and Prevention, HHS

ACTION: Program announcement number 01163 correction.

SUMMARY: The Centers for Disease Control and Prevention published Program Announcement 01163 for HIV Prevention Projects for Community-Based Organizations Targeting Young Men of Color Who Have Sex With Men

FOR FURTHER INFORMATION CONTACT: David A. Wilson, 770-488-2692

Correction

In the **Federal Register** of June 21, 2001, in FR Vol 66, No. 120, Page 33254, first line, third column, correct date to read On or Before July 31, 2001. On Page 33255, second column, under J. Where to Obtain Additional Information, third paragraph, phone number for David A. Wilson should read: 770-488-2692.

Dated: June 22, 2001.

John L. Williams,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
(CDC).*

[FR Doc. 01-16247 Filed 6-27-01; 8:45 am]

BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Centers for Disease Control and
Prevention**

**Opportunity To Collaborate in the
Evaluation of Topical Microbicides To
Reduce Transmission of Human
Immunodeficiency Virus (HIV) Among
Men Who Have Sex With Men (MSM)**

AGENCY: Centers for Disease Control and Prevention, 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 (EpiB), has an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides for rectal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in MSM.

SUMMARY: The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP-SE) of the National Center for 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, biotechnological, or other companies who hold a proprietary position on microbicides developed for vaginal use that are ready for phase III trials. The selected company and CDC would execute an "Agreement" to evaluate the company's microbicides for safety and acceptability of topical microbicides designed for vaginal application to reduce HIV transmission when applied to the rectal mucosa. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in MSM. Each collaboration would have an expected duration of two (2) 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 by MSM as well as heterosexual men and women.

Confidential proposals, preferably 10 pages or less (excluding appendices), are solicited from companies with patented or licensed agents which have undergone sufficient clinical testing to be: (1) Currently under an IND approved by the Food and Drug Administration (FDA); (2) have completed at least one phase I and one phase II trial for vaginal application of the microbicide as of December 31, 2001; and (3) be planning to begin a phase III trial for vaginal use which is anticipated to begin enrollment prior to December 31, 2002.

DATES: Formal proposals must be submitted no later than July 30, 2001.

ADDRESSES: Formal proposals should be submitted to Jeff Efird, MPA, Epidemiology Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E-45, Atlanta, GA 30333; Phone: (direct) 404-639-6136, (office) 404-639-6130; Fax: 404-639-6127; e-mail: JLE1@cdc.gov. Scientific questions should be addressed to Dawn K. Smith, MD., Epidemiology Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E-45, Atlanta, GA 30333; Phone: (direct) 404-639-6165, (office) 404-639-6146; Fax: 404-639-6127; e-mail: Dsmith1@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 E-67, Atlanta, GA 30333; Phone: (direct) 404-639-6270, (office) 404-639-6270; Fax: 404-639-6266; e-mail: TEO1@cdc.gov.

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch 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

for the evaluation of topical microbicides through late preclinical, phase I, phase II, and proof-of-concept clinical trials.

Technology Sought

EpiBr now seeks potential collaborators having licensed or patented agents for use as vaginal microbicides and:

- (1) Will have at least one phase I and one phase II trial for vaginal use completed by December 31, 2001;
- (2) Will have a phase III trial for vaginal use planned to begin enrollment prior to December 31, 2002;
- (3) Have manufacturing arrangements for production of clinical trial-grade product (and applicator if necessary) under Good Manufacturing Process (c-GMP) standards; and
- (4) Are willing to provide a formulation and dosage appropriate for rectal application.

**NCHSTP and Collaborator
Responsibilities**

The NCHSTP anticipates that its role may include, but not be limited to, the following:

- (1) Providing intellectual, scientific, and technical expertise and experience to the research project;
- (2) Planning and conducting preclinical (in-vitro and in-vivo) research studies of the agent and interpreting results;
- (3) Publishing research results;
- (4) Depending on the results of these preclinical investigations, NCHSTP may elect to conduct additional research with macaques to evaluate safety and/or efficacy proof-of-concept; and
- (5) Depending on the results of preclinical and/or macaque studies and FDA approval, NCHSTP may elect to conduct phase I/II clinical trials of the agent.

The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

- (1) Providing intellectual, scientific, and technical expertise and experience to the research project;
- (2) Participating in the planning of research studies, interpretation of research results and, as appropriate, joint publication of conclusions;
- (3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and
- (4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.