

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. Steketee, 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]

BILLING CODE 4163-18-P

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.