

Scholars who received support in FY 1999.

Estimate of Burden: The Foundation estimates that, on average, 0.5 hours per Scholar applying for funds will be required to complete the Payment Request Form, for a total annual burden of 136.5 hours for all applicants.

Respondents: Individuals.

Estimated Number of Responses: 273.

Estimated Total Annual Burden on Respondents: 136.5 hours.

Dated: May 4, 2000.

Louis H. Blair,

Executive Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00063]

Interdisciplinary Evaluation of Combination Therapy for Uncomplicated Malaria; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for Interdisciplinary Evaluations of Combination Therapy for Uncomplicated Malaria. CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010", a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the focus areas of Immunization and Infectious Diseases. The purpose of the program is to evaluate the effectiveness of combination antimalarial therapy at district or multidistrict level in sub-Saharan Africa.

B. Eligible Applicants

Assistance will be provided only to Ifakara Health and Research Development Center (IHRDC), in Ifakara, United Republic of Tanzania. No other applications are solicited.

The United Republic of Tanzania is the only country located in sub-Saharan Africa where large portions of the country are located in areas of active, and intense, transmission of the parasite *Plasmodium falciparum*. They represent one of only a few countries where drug policy reform is underway because of antimalarial drug resistance and is actively engaged in developing and

testing strategies for addressing the problem of antimalarial drug resistance. Antimalarial drug resistance to chloroquine, the traditional first-line treatment for uncomplicated malaria, has intensified to a point where the Ministry of Health has decided to switch to an alternative medicine, sulfadoxine/pyrimethamine (SP), for first-line treatment of malaria. Because of concerns that this strategy will be short lived due to pre-existing levels of drug resistance to SP, the Ministry of Health is keenly interested in understanding potential future options for addressing this pressing public health challenge.

The IHRDC in Ifakara, Tanzania, is a non-government organization that comes under the jurisdiction of the United Republic of Tanzania, Ministry of Health. The Ministry of Health has oversight of the IHRDC and must approve all actions taken on behalf of the United Republic of Tanzania. IHRDC is the only institution in sub-Saharan Africa that is located in an area of very intense malaria transmission, that is located in a country that is poised to adopt a national malaria treatment policy of SP while actively engaged in investigating future treatment options; is actively engaged in research activities that are directly related to the objectives listed above; and has the needed experience and capacity. Because of its work in malaria for more than a decade, IHRDC is an internationally respected research institution. Investigators at IHRDC have a detailed understanding of the epidemiologic patterns and geographic distribution of malaria infection and transmission in their area, are actively engaged in using state-of-the-art techniques for evaluating antimalarial drug resistance, and have needed and proven expertise in socio-behavioral research related to malaria. In addition, the IHRDC maintains a demographic surveillance system (DSS) covering approximately 55,000 individuals, allowing for measurement of public health impact of malaria treatment policies, and, through its existing collaborative links to other institutions and projects, has the ability to access comparable data from 2 additional DSS data bases (covering a total population of over 300,000 individuals). The IHRDC is the only organization that has the capacity to carry out large-scale community-based public health interventions, to conduct malaria research, and to correctly diagnose drug resistant malaria infections in its laboratories and field activities. They have the required field experience and demonstrated capacity

in areas directly related to all 6 principal objectives of this proposed evaluation: (1) Using state-of-the-art methods of diagnosing antimalarial drug resistance, including in vivo, in vitro, and molecular methods; (2) monitoring for changes in gametocytemia rates; (3) socio-behavioral research related to malaria, malaria drug use practices, and malaria treatment seeking practices; (4) economics of malaria and malaria treatment; (5) research into the process development of public health policy related to malaria; and (6) monitoring for public health impact, including on a population level.

C. Availability of Funds

Approximately \$500,000 is available in FY 2000 to fund one award. It is expected that the award will begin on or about August 30, 2000, and will be made for a 12-month budget period within a project period of up to five years. The funding estimate may change.

Continuation awards within an approved project period may be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for conducting the activities under 1. (Recipient Activities) and CDC will be responsible for conducting the activities under 2. (CDC Activities).

1. Recipient Activities

a. Identify an appropriate set of districts for the evaluation of a pilot policy of antimalarial combination therapy, including comparison areas using SP monotherapy for treatment of all cases of uncomplicated malaria.

b. Design a multifaceted evaluation program to determine the effectiveness of antimalarial combination therapy on inhibiting development of drug resistance and decreasing malaria transmission, as well as to elucidate programmatic, behavioral, economic, or policy aspects of combination therapy that could either enhance or limit this effectiveness.

c. Define, collect, and analyze baseline data: Collect baseline data so that the public health impact of the interventions can be evaluated (including impact on mortality rates).

d. Carry out the evaluation activities.

e. Measure the effect of the national treatment policy compared with the pilot policy of combination therapy in terms of (1) inhibiting the development of resistance to SP; (2) interrupting

transmission of the parasite; and (3) describing the behavioral, economic, and policy determinants of the policies.

f. Disseminate research results by appropriate methods such as publication in journals, presentation at meetings, conferences, etc.

g. Develop a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

2. CDC Activities

CDC will provide technical assistance in the design and conduct of the research as needed to possibly include:

a. Providing assistance in the evaluation methods and analytic approach.

b. Performing selected laboratory tests, as requested by IHRDC, including analysis of drug resistance conferring mutations in parasite samples by polymerase chain reaction (PCR) or gene sequencing, testing of biologic samples for presence of antimalarial drugs; testing of pharmaceutical samples for quality.

c. Assisting in data collection, data management, analysis of research data, interpretation, and dissemination of research findings.

d. Collaborating in the design of the evaluation.

e. Providing educational and training materials, as appropriate.

f. Assisting in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 10 double-spaced pages, printed on one side, with one inch margins, and un-reduced font.

F. Submission and Application Deadline

Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are in the application kit. On or before June 30, 2000, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

G. Evaluation Criteria

The application will be evaluated against the following criteria by an independent review group appointed by CDC.

1. Background and Need (10 points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this cooperative agreement program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this program.

2. Capacity (30 points total)

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. This includes the capacity to conduct quality laboratory measurements. (15 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research and programs related to that proposed as evidenced by curriculum vitae, publications, etc. (10 points)

c. Extent to which applicant includes letters of support from non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate the author's commitment to participate as described in the operational plan. (5 points)

3. Objectives and Technical Approach (60 points total)

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this program and which are measurable and time-phased. (10 points)

b. Extent to which the applicant identifies appropriate populations for study, with an adequate size to evaluate the program. Extent to which adequate procedures are described for the protection of human subjects. (10 points)

c. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all recipient activities. Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. 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, and (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. The extent to which applicant describes the existence of or plans to establish partnerships. (30 points)

d. Extent to which applicant provides a detailed and adequate plan for evaluating study results (including laboratory data and data on prescribing practices), as well as plans for evaluating progress toward achieving project objectives. (10 points)

4. Budget (not scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds.

5. Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Annual progress reports,
2. Financial status report, no more than 90 days after the end of the budget period, and
3. Final financial status 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 in the application kit.

- AR-1 Human Subjects Requirements
- AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, Sections

301(a) [42 U.S.C. 241(a)], 307 [42 U.S.C. 2421], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

If you have any questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone (770) 488-2764, Email address vxm7@cdc.gov.

For program technical assistance, contact: Peter B. Bloland, DVM, MPVM, Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, Mailstop F-22, Atlanta, GA 30333, Telephone (770) 488-7760, Email address: pbloland@cdc.gov.

Dated: May 4, 2000.

Henry S. Cassell III,

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

[FR Doc. 00-11647 Filed 5-9-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee on Prevention of Intimate Partner Violence and Sexual Violence and the Injury Research Grant Review Committee (IRGRC): Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee and conference call committee meetings.

Name: Subcommittee on Prevention of Intimate Partner Violence and Sexual Violence of the IRGRC.

Times and Dates: 6:30 p.m.-9 p.m., June 4, 2000. 8 a.m.-4 p.m., June 5, 2000.

Place: The Westin Atlanta Airport, 4736 Best Road, College Park, Georgia 30337

Status: Open: 6:30 p.m.-7 p.m., June 4, 2000. Closed: 7 p.m.-9 p.m., June 4, 2000, through 4 p.m., June 5, 2000.

Purpose: The Subcommittee advises IRGRC on the technical and scientific merit of injury prevention research grant applications on Prevention of Intimate Partner Violence and Sexual Violence.

Matters To Be Discussed: Agenda items include a description of the Subcommittee's responsibilities and review process, and review of grant applications.

Name: Injury Research Grant Review Committee.

Time and Date: 4:30 p.m.-5:30 p.m., June 5, 2000.

Place: The Westin Atlanta Airport, 4736 Best Road, College Park, Georgia 30337

Status: Open: 4:30 p.m.-4:45 p.m., June 5, 2000. Closed: 4:45 p.m.-5:30 p.m., June 5, 2000.

Purpose: This committee is charged with advising the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the scientific merit and technical feasibility of grant applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focus on prevention and control and to support injury prevention research centers.

Matters To Be Discussed: Agenda items include the purpose of the meeting and discussion and vote on the report of the Subcommittee on Prevention of Intimate Partner Violence and Sexual Violence.

Beginning at 7 p.m., June 4, through 4 p.m., June 5, the Subcommittee on Prevention of Intimate Partner Violence and Sexual Violence of the IRGRC will meet, and from 4:45-5:30 p.m., June 5, IRGRC will meet to conduct a review of grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information:

Linda L. Dahlberg, Ph.D., Acting Executive Secretary, IRGRC, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, M/S K60, Atlanta, Georgia 30341-3724, telephone 770/488-4496.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 3, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-11648 Filed 5-9-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 65 FR 4979, dated February 2, 2000) is amended to reflect the restructuring of the Office of Health and Safety, Office of the Director, Centers for Disease Control and Prevention (CDC).

Section C-B, Organization and Functions, is hereby amended as follows:

Add the following item to the mission statement for the *Office of Health and Safety (CA1)*: (7) provides advice and counsel to the CDC Office of the Director on health and safety related matters.

After the functional statement for the *Office of the Director (CA11)*, insert the following:

External Activities (CA112). (1) Manages CDC regulatory programs for which the Office of Health and Safety is responsible (i.e., import permit program [42 CFR 71], laboratory registration/select agent transfer program [42 CFR 72.6], and infectious agents shipping regulation [42 CFR 72]; (2) develops and reviews national safety guidelines including the "CDC/NIH Biosafety in Microbiological and Biomedical Laboratories" and the infectious agent shipping regulations; (3) participates in CDC, HHS, and interagency committees and workgroups considering matters related to laboratory safety including the public health response to bioterrorism; (4) provides consultations and technical assistance to State and local health departments on matters related to laboratory safety; (5) provides consultation and technical assistance to CDC laboratories located outside the US; (6) manages the WHO Collaborating Center for Applied Biosafety and Training at CDC; (7) participates in other domestic and international laboratory safety activities as requested.

Resource Management Activity (CA113). (1) Develops and coordinates budgets for OHS; (2) plans, coordinates, and provides administrative, fiscal and management assistance, including personnel, travel, training, and contract