Board of Governors of the Federal Reserve System, April 4, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Linkage of International Collaboration and Research Programs for Prevention and Control of Malaria

Announcement Type: New.

Funding Opportunity Number: RFA CI05–062.

Catalog of Federal Domestic Assistance Number: 93.283.

Application Deadline: May 23, 2005.

I. Funding Opportunity Description

Authority: 42 U.S.C. 241(a); 42 U.S.C. 2421.

Background

Burden of malaria in Africa and Asia: Each year, malaria causes an estimated 500 million infections and more than one million deaths. The main risk groups in highly endemic areas, such as in most of sub-Saharan Africa, are children less than five years of age and pregnant women. Malaria drains economies in Africa, Asia, and the Americas—causing a loss of up to six percent of Gross National Product (GNP) from lost productivity and health service costs, with over 50 percent of the world's population at risk for malaria. Thus, prevention of malaria and, when it occurs, its effective treatment, are high public health priorities in endemic countries. There is a paucity of data on the burden of malaria from Asia.

Malaria control: Three major tools are currently used to control malaria: preventing and treating disease with drugs, reducing human-vector contact such as by insecticide treated mosquito nets (ITNs), and controlling mosquitoes (*e.g.* spraying of insecticides).

The use of drugs for treatment and prevention remains one of the main pillars for the Roll Back Malaria initiative (RBM), but the rampant spread of drug resistance of the malaria parasite to the cheap and most commonly available antimalarials is a major problem. Nevertheless, drug development has improved considerably in the last five years and the outlook for new antimalarials is now better than it has been for decades. Much needs to be done to test their safety and efficacy and further work is needed to ensure that they are optimally used and made accessible to the target population.

Reduction of human-vector contact by use of ITNs has been shown to reduce under-five mortality by 18 percent in Africa and ITNs are now one of the main RBM strategies. Despite the clear evidence of their efficacy in Africa, very little is known about their impact in Asia. In some regions of Asia the vector bites early in the evening or morning thus ITNs may not be the optimal prevention tool and other methods that reduce human-vector contact should be explored, including DEET retaining repellents.

Vector control has saved millions of lives worldwide and indoor residual spraying with insecticides (IRS) continues to play a major role in much of Latin America and Asia, but its cost, logistical complexity and moderate efficacy made it poorly suited for rural areas of sub-Saharan Africa.

Nevertheless advances in genomics (including the mapping of the mosquito and parasite genome), biotechnology, and mapping using geographical information systems, present exiting new opportunities for the development and employment of more cost-effective tools that take aim at the mosquito.

Global collaboration: Although important progress in malaria control has been accomplished in recent years, much more could have been done. This slow progress is partly due to the lack of funding. CDC recognizes that this is also due to lack of coordination between research groups, and between researchers and donors, policy makers, and Government Ministries responsible for implementation. After decades of neglect the international community is showing a renewed interest in controlling malaria. This has resulted in new initiatives, including the RBM initiative, Global Fund Initiative (GFATM) and Malaria Vaccine Initiative as well as significant new funding for both research and program development. Global collaboration is now more critical than ever to ensure translation of this commitment into action and avoid fragmentation of efforts. Many of these studies require well-coordinated multi-center trials to allow rapid accumulation of data and account for the geographical variations in drug sensitivity, frequency of host-genetic polymorphism, cultural preferences and economics.

Purpose

The purpose of this program is to strengthen international collaborative efforts with leading European Institutions to expedite the identification, evaluation and implementation of malaria control strategies in sub-Saharan Africa and Asia. The aim is to move forward the RBM agenda of increasing access to case management and preventive interventions against malaria by promoting work in a complementary way on key issues relevant to the control of 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 addresses the ''Healthy People 2010'' focus areas of HIV, Immunization, Infectious Diseases and Public Health Infrastructure. For the conference copy of ''Healthy People 2010'', visit the Internet site *http://www.health.gov/healthy-people.*

Measurable outcomes of the program will be in alignment with one (or more) of the National Center for Infectious Disease (NCID) priority areas identified in ''Protecting the Nation's Health in an Era of Globalization: CDC's Global Strategy for Addressing Infectious Diseases''. Priority areas for this cooperative agreement include: (1) Applied research on diseases of global importance, (2) application of proven public health tools, (3) global initiatives for disease control and, (4) public health training and capacity building.

Research Objectives

- Nature of the research problem.

Burden and control of malaria in India: Conventional estimates of the global burden of malaria suggest that over 90 percent of the burden occurs in Africa. There is however a paucity of reliable data from Asia, particularly India, which has a population of 1 billion, more than the entire African continent. India's National Vector Borne Disease Control Programme reports less than two million cases annually, but recent estimates from the World Health Organization (WHO) suggest this may be as high as 45–100 million. Although transmission is lower than in Africa, less malarial immunity is acquired during a lifetime of exposure so that even adults remain at risk of dying from severe malaria. Establishment of more accurate estimates of the burden of malaria, and appropriate evidenced-based treatment and prevention policies are essential to minimizing this public health threat of malaria in India.

ITNs and IRS alone can reduce malaria transmission by as much as 90 percent. Despite this, a significant

proportion of the population remains infected. Evidence from Thailand and Vietnam suggests that sustained reductions in transmission may be achieved by combining vector control with use of antimalarials that contain Artemisinin derivatives. Artemisinin containing combination therapy (ACT) offers great hope for the control of malaria. These drugs not only provide fast and highly effective treatment, but also have the potential to interrupt transmission by markedly reducing gametocyte development of the parasite and enhance the effects of vector control. It is likely that these promising results from South East Asia are applicable to large regions in India with similar transmission patterns and vector behavior, and this now needs to be evaluated.

Malaria control in pregnancy: Intermittent preventive therapy (IPT) and ITNs are the two main strategies for malaria control in pregnancy in areas with moderate to high malaria transmission. Nevertheless, the scientific evidence on which these policy recommendations are based is incomplete and many research questions remain. For example it is unclear whether IPT or ITNs work in areas with low malaria transmission. Furthermore, for IPT there is a heavy reliance on sulfadoxine-pyrimethamine (SP) and chloroquine and there is an urgent need to identify alternative drugs as both these drugs have increasing drug resistance. Despite the recognition that malaria poses an important problem in pregnancy, the arsenal of drugs for the prevention and control of malaria in pregnancy (MIP) lags behind that for children. This can be attributed to the systematic exclusion of pregnant women from trials for fear of toxicity to the fetus, the scarcity of resources specific for this high-risk group, and to some extent to the lack of global coordination of research agendas.

Recently a new global malaria in pregnancy research consortium (MIP Consortium) of over 40 research institutions, together with the World Health Organization (WHO/RBM), identified the key priority areas of research for malaria control in pregnancy. These include: (1) The determination of the burden of malaria in pregnancy in areas of low transmission, such as in Asia, to enhance the ability of public health programs to develop and target appropriate intervention approaches in these regions; (2) studies of the pharmacokinetics, safety and efficacy of alternative drugs for treatment and prevention of malaria in pregnancy, and; (3) studies that determine how best to use ITNs and antimalarial drugs in combination to maximize the prevention benefit and limit adverse exposures in pregnancy.

Malaria control in children:

Treatment: SP has been the mainstay of malaria treatment in many countries in Africa over the last 10 years, yet resistance to SP is emerging rapidly. Artemisinin derivatives combined with other antimalarial (ACTs) have the potential to improve cure rates and reduce the development of drug resistance. There are a number of artemisinin-based combinations that have or will become available and require evaluation to assist in policy formulation.

New drug approaches to malaria prevention in children: Daily or weekly malaria prophylaxis is no longer recommended for malaria endemic countries and new strategies for the prevention of malaria involving drugs are required. One such strategy is IPT, and consists of administration of full treatment doses given presumptively (regardless of the presence of malaria) at predefined intervals to provide prolonged periods of protection. This approach is now widely advocated for pregnant women attending antenatal care (IPTp) and is being evaluated (by CDC and others) for the prevention of severe malaria and anemia in infants (IPTi). More research is required to further develop the concept of IPT in other high-risk populations such as in young children admitted with severe malarial anemia requiring a blood transfusion. Previous studies have indicated that this group is at very high risk of rebound severe anemia and death in the six-month period post-discharge. Prolonged periods of protection from malaria from intermittent antimalarial treatment post discharge (IPTpd) may prevent re-infection and increase hematological recovery and possibly reduce death due to rebound severe anemia.

HIV-infected individuals: The burden of malaria is exacerbated by the advent of HIV, which increases susceptibility to malaria, particularly in pregnancy. Conversely acute malaria is associated with transient rises in HIV viral load. It is unclear whether repeated frequent malaria infections in areas with intense malaria transmission is associated with increased AIDS disease progression, and if so, whether prevention of malaria can reduce AIDS disease progression. Furthermore with the wide spread use of antimalarials and with the introduction of anti-retroviral drugs in Africa there is an urgent need to determine the safety and kinetics of these drugs when used at the same time.

- Scientific knowledge to be achieved through research supported by this program.

India & Asia:

1. Identifying the burden of malaria in selected Asian countries, including India.
2. Identifying potential interventions to reduce the burden of malaria in pregnant women in India.
3. Evidence of the effectiveness of reducing malaria transmission in a large region through multi-pronged approach that uses a combination of vector control measures and appropriate treatment and prevention of malaria with artemisinin containing combination therapies.

Pregnant Women:

4. Evidence of the pharmacokinetics, safety and efficacy of new antimalarials for treatment and prevention of MIP.
5. Knowledge of how best to combine ITNs with antimalarials in the prevention of malaria in pregnancy.

Children:

6. Evidence of the safety and efficacy of new antimalarials for the treatment of non-severe malaria in children.
7. The degree to which IPT is effective for the prevention of severe malaria and anemia among children.

HIV infected patients:

8. Knowledge of the safety and kinetics of ARVs and antimalarials in HIV infected persons when used at the same time.
9. Knowledge of the impact of malaria prevention on the rate of HIV disease progression.

- Objectives of this research program.

Strengthen international collaborative efforts to expedite the identification, evaluation, and implementation of malaria control strategies in sub-Saharan Africa and Asia.

- Identify the types of research and experimental approaches that are being sought to achieve the objectives.

The recipient institution will work with CDC on a package of research and policy into practice activities, mainly in India and Africa, which require a range of experimental approaches and activities. These include the development and evaluation of epidemiological survey tools for the rapid assessment of the burden of malaria in regions with low transmission, such as India. CDC has developed rapid assessment tools for Africa, providing the groundwork for this activity, but these tools need to be field tested and adopted to the Asian setting. Further experimental approaches include the design and coordination of multi-center trials of the treatment and prevention of malaria, and the application of specific statistical

methods that allow individual patient data meta-analysis of these multi-centre trials. Lastly, the global malaria in pregnancy research consortium requires a secretariat to coordinate the activities for the consortium.

Activities

Recipient activities for this program are as follows:

India and Asia:

1. Provide technical support to the Malaria Research Council (Jabalpur, Madhya Pradesh, India) for studies that assess the burden of malaria in pregnancy in India and for community and clinical studies by the Malaria Research Council related to MIP and malaria in children and adults.

2. Provide technical assistance to the WHO Southeast Asia Regional Office (SEARO) to assess the burden of malaria in pregnancy in select Asian countries and to develop appropriate standardized rapid assessment tools for this purpose.

Malaria in Pregnancy:

3. Serve as the global Secretariat for the MIP Consortium to:

• Provide a platform that enhances collaboration between research groups and international organizations working on malaria in pregnancy.

• Coordinate interventional research relevant to the control of malaria in pregnancy and to promote the quality of such research by encouraging use of standardized research methods among consortium members.

• Act as an advocate for malaria in pregnancy research and mobilize funding.

• Coordinate or participate in the development of research grants, and of research protocol development and execution of multi-centre trials.

• Identify, evaluate and implement appropriate new interventions for the treatment and prevention of malaria in pregnancy in Africa and Asia.

4. Determine the pharmacokinetics of new antimalarials for use in pregnancy.

Children:

5. Design and conduct studies of IPT in the post-discharge period (IPTpd) in children with severe malaria to determine whether IPTpd is effective in preventing rebound severe malaria and anemia.

HIV and Malaria:

6. Design and conduct studies to assess drug interaction between ARVs and antimalarials.

7. Provide technical support for grant writing, design, and conduct of studies that determine the role of malaria on HIV disease progression.

Capacity building:

8. Strengthen research capacity for endemic countries by providing diploma, Master's and PhD level training in tropical medicine to professionals from malaria endemic countries involved with CDC malaria-related activities in Africa and Asia.

9. Provide technical support to select malaria endemic sub-Saharan African countries to achieve RBM targets related to MIP and children.

Research synthesis and dissemination of results:

10. Coordinate research synthesis and provide individual patient data meta-analysis of the multi-centre trials in children and pregnant women.

11. Participate in the dissemination of research results or other activities through written publications, including peer-reviewed journals, oral presentations, or other means.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC Activities for this program are as follows:

• Provide technical assistance in the design and conduct of the activities, including evaluation methods and analytic approach.

• Provide consultation and assistance on methods for treatment of malaria, enhancing capacity at different levels (local, national) to increase use of prevention measures including insecticide treated bed nets, or prevention of malaria and its adverse consequences during pregnancy.

• Provide consultation and assistance on operations research study designs that may be identified and carried out by recipient or MIP Consortium partners.

• Participate as needed in data collection, data management, analysis of research data, interpretation, and dissemination of research findings.

• Provide assistance in design of the evaluations.

• Provide assistance in the development of any research protocols for Institutional Review Board (IRB) review by all cooperating institutions participating in research projects. The CDC IRB will review and approve the protocol initially and on at least an annual basis until research projects are completed.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Mechanism of Support: U01.

Fiscal Year Funds: FY05.

Approximate Total Funding: $400,000. (This amount is an estimate, and is subject to availability of funds. This amount includes both direct and indirect costs.)

Approximate Number of Awards: 1.

Approximate Average Award: $400,000. (This amount is for the first 12-month budget period.)

Floor of Award Range: None.

Ceiling of Award Range: $400,000. (This ceiling is for the first 12-month budget period and includes both direct and indirect costs.)

Anticipated Award Date: August 15, 2005.

Budget Period Length: 12 months.

Project Period Length: Five years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

• Public nonprofit organizations.
• Private nonprofit organizations.
• Small, minority, women-owned businesses.
• Universities.
• Colleges.
• Research institutions.
• Hospitals.
• Community-based organizations.
• Faith-based organizations.
• Federally recognized Indian tribal governments.
• Indian tribes.
• Indian tribal organizations.
• State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).
• Political subdivisions of States (in consultation with States).

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Special Requirements

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Applicant must have experience and current activities coordinating international networks that are relevant to malaria in pregnancy research such as designation as a coordinating center or Secretariat; one or more of the networks must include European institutions.

Applicant must have the capacity to conduct meta-analysis, this may be through an well-established relationship with a group recognized for meta-analysis work.

Applicant must have experience and current capability to conduct malaria vector control research in partnership with other institutions.

Applicant must have an institutional link and access to a Liquid Chromatography/Mass Spectrometry bioanalytical facility. The facility must be recognized as a regional analytical reference site, preferably one that includes some malaria endemic countries in Africa and Asia.

Applicant must have experience in conducting studies of anti-retroviral drug interaction including the potential interactions between anti-retrovirals and anti-malarials.

Applicant must have long-term technical and research collaborative malaria-related activities in Africa and Asia; in addition, the applicant must have an established relationship with the Malaria Research Council of India and with the Kenya Medical Research Institute/Centers for Disease Control and Prevention program.

Applicant must have an established multi-level academic program suitable for training persons from malaria endemic countries in fields suitable for malaria research and which leads to a recognized diploma, certificate, and/or degree.

Applicant must have experience providing technical support to WHO or similar international organizations, endemic country research institutes and/or Ministries of Health for malaria in pregnancy development and program implementation.

Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.

The applicant must document eligibility by providing the following documentation which should be attached in an appendix to the application: (a) Evidence of role with malaria research related consortium(s) including current activities and evidence of the inclusion of European-based organizations; (b) evidence of organizational capacity to conduct meta analysis; this may be a letter from the unit within the organization that outlines their capability and support for the defined work; (c) evidence of organization's past and current work conducted in partnership with other institutions to conduct malaria vector control research; (d) evidence of an institutional link and access to a Liquid Chromatography/Mass Spectrometry bioanalytical facility that is a recognized regional analytical reference site. This may be a letter of support from the facility; (e) evidence of experience in conducting studies of anti-retroviral drug interaction including the potential interactions between anti-retrovirals and anti-malarials; (f) evidence of current malaria research collaborations in sub-Sahara Africa including letters of support from the Malaria Research Centre (Jababur, Madhya Pradesh, India) for this work and the Kenya Medical Research Institute/Centers for Disease Control and Prevention program in Kisumu, Kenya; (g) evidence of an active multi-level academic program for training persons from malaria endemic countries, especially those in Africa; and (h) evidence of experience providing technical support to WHO or a similar international organization, endemic country research institutes and/or Ministries of Health for malaria in pregnancy development and program implementation.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

Individuals Eligible to Become Principal Investigators

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

Additional Principal Investigator qualifications are as follows:

(a) Experience conducting field epidemiologic research in malaria in pregnancy in sub-Sahara Africa or Asia that resulted in one or more published articles in a peer reviewed journal.

(b) Experience mentoring local staff involved in an academic program from a developing country in Africa or Asia.

(c) Experience setting up and running a research consortium.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.* Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Application Submission

Application: Follow the PHS 398 application instructions for content and formatting of your application. If the instructions in this announcement differ in any way from the PHS 398 instructions, follow the instructions in this announcement. For further assistance with the PHS 398 application form, contact PGO–TIM staff at 770–488–2700, or contact GrantsInfo, telephone (301) 435–0714, e-mail: *GrantsInfo@nih.gov.*

Your research plan should address activities to be conducted over the entire project period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number,

access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

This announcement uses the non-modular budgeting format.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

Application Deadline Date: May 23, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you submit your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on application content, submission address, and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html.*

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board approvals are in place.
- Reimbursement of pre-award costs is not allowed.
- Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services.

Equipment may be purchased if deemed necessary to accomplish program objectives, however, prior approval by CDC officials must be requested in writing.

- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.
- The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required.)
- All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.
- You must obtain annual audit of these CDC funds (program-specific audit) by a U.S.—based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.
- A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-RFA CI05–062, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

At the time of submission, three additional copies of the application, and all appendices must be sent to: Dr. Trudy Messmer, RFA CI05–062, National Center for Infectious Diseases (NCID), CDC, 1600 Clifton Road, MS C–19, Atlanta, GA 30333. E-mail: *TMessmer@cdc.gov.*

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

The applicant is required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the following criteria equally in assigning the application's overall score, weighting them as appropriate for the application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The review criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score:

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of title 45 CFR part 46 for the protection of human subjects?

Inclusion of Women and Minorities in Research: Does the application adequately address 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.

Budget: (This will not be scored) The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

V.2. Review and Selection Process

The application will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by NCID. An incomplete application or application that is non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

A complete and responsive application will be evaluated for scientific and technical merit by a Special Emphasis Panel comprised of external experts convened by the NCID Office of Extramural Research in accordance with the review criteria listed above. As part of the scientific merit review, the application will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit by the review group, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second programmatic level review by CDC senior staff.

Award Criteria: Criteria that will be used to make award decisions during the programmatic review include:

- Scientific merit (as determined by peer review).
- Availability of funds.
- Programmatic priorities.

V.3. Anticipated Award Date

August 15, 2005.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and CDC. The NoA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR parts 74 and 92.

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- 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.
- AR–22 Research Integrity.
- AR–24 Health Insurance Portability and Accountability Act Requirements.
- AR–25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement.

For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2700.

For scientific/research issues, contact: Dr. Trudy Messmer, Scientific Review Administrator, 1600 Clifton Road, MS C–19, Atlanta, GA 30333. Telephone: 404–639–3770. E-mail: *TMessmer@cdc.gov.*

For questions about peer review, contact: Ms. Barbara Stewart, Public Health Analyst, 1600 Clifton Road, MS C–19, Atlanta, GA 30333. Telephone: 404–639–3770. E-mail: *BStewart@cdc.gov.*

For financial, grants management, or budget assistance, contact: Steward Nichols, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770–488–2788. E-mail: *SHN8@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Additional background information can be found at: *http://www.cdc.gov/malaria/.*

Dated: April 4, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1296–N2]

Medicare Program; Request for Nominations to the Advisory Panel on Ambulatory Payment Classification Groups; Extension of Nominations Deadline

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice extends the deadline for nominations of members to the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel). The original request for nominations was published in the **Federal Register** on February 25, 2005. (70 FR 9336) Six vacancies will exist on the Panel as of March 31, 2005.

The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. The advice provided by the Panel will be considered as CMS prepares its annual updates of the hospital Outpatient Prospective Payment System (OPPS) through rulemaking.

The panel was recently rechartered for a 2-year period through November 21, 2006.

Nominations: Nominations will be considered if received no later than May 9, 2005. Mail or deliver nominations to the following address: CMS; Attn: Shirl Ackerman-Ross, Designated Federal Officer (DFO), Advisory Panel on APC Groups; Center for Medicare Management (CMM), Hospital & Ambulatory Policy Group (HAPG), Division of Outpatient Care (DOC); 7500 Security Boulevard, Mail Stop C4–05–17; Baltimore, MD 21244–1850.

Web site: For additional information on the APC Panel and updates to the Panel's activities, search our Web site at: *http://www.cms.hhs.gov/faca/apc/default.asp.*

Advisory Committees' Information Lines: You may also refer to the CMS Advisory Committee Information Hotlines at 1–877–449–5659 (toll-free) or 410–786–9379 (local) for additional information.

FOR FURTHER INFORMATION CONTACT: Persons wishing to nominate individuals to serve on the Panel or to obtain further information can also contact Shirl Ackerman-Ross, the DFO, at *APCPanel@cms.hhs.gov* or call 410–786–4474. News media representatives should contact the CMS Press Office at 202–690–6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act), as amended and redesignated by sections 201(h) and 202(a)(2) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), respectively, to establish and consult with an expert, outside advisory panel on Ambulatory Payment Classification (APC) groups.

The Panel meets up to three times annually to review the APC groups and to provide technical advice to the Secretary and the Administrator concerning the clinical integrity of the groups and their associated weights. CMS considers the technical advice provided by the Panel as we prepare the proposed rule that proposes changes to the OPPS for the next calendar year.

The Panel may consist of up to 15 representatives who are full-time employees (not consultants) of Medicare providers, which are subject to the OPPS, and a Chair.

The Administrator selects the Panel membership based upon either self-nominations or nominations submitted by providers or interested organizations.

The current Panel members are: (The asterisk [*] indicates a Panel member whose term expires on March 31, 2005.)

- E.L. Hambrick, M.D., J.D., a CMS Medical Officer
- Marilyn K. Bedell, M.S., R.N., O.C.N.
- Albert Brooks Einstein, Jr., M.D.
- Lee H. Hilborne, M.D.*
- Stephen T. House, M.D.*
- Kathleen P. Kinslow, C.R.N.A., Ed.D.*
- Mike Metro, R.N.*
- Sandra J. Metzler, M.B.A., R.H.I.A.
- Gerald V. Naccarelli, M.D.*
- Frank G. Opelka, M.D.
- Louis Potters, M.D.
- Lou Ann Schraffenberger, M.B.A., R.H.I.A.
- Judie S. Snipes, R.N., M.B.A., C.H.E.
- Lynn R. Tomascik, R.N., M.S.N., C.N.A.A.
- Timothy Gene Tyler, Pharm.D.
- William A. Van Decker, M.D., J.D.*

Panel members serve without compensation, according to an advance written agreement; however, travel, meals, lodging, and related expenses are reimbursed in accordance with standard Government travel regulations. CMS has a special interest for ensuring that women, minorities, and the physically challenged are adequately represented on the Panel. CMS further encourages nominations of qualified candidates from those groups.

The Secretary, or his designee, appoints new members to the Panel from among those candidates determined to have the required expertise. New appointments are made in a manner that ensures a balanced membership.

II. Criteria for Nominees

All nominees must have technical expertise that enables them to participate fully in the work of the Panel. Such expertise encompasses hospital payment systems, hospital medical-care delivery systems, outpatient payment requirements, Ambulatory Payment Classification (APC) Groups, Physicians' Current Procedural Terminology Codes (CPTs), the use and payment of drugs and medical devices in the outpatient setting, and other forms of relevant expertise.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years experience and currently be employed full-time in his or her area of expertise. Members of the Panel serve overlapping 2, 3, and 4-year terms, contingent upon the rechartering of the Panel.

Any interested person may nominate one or more qualified individuals. Self-nominations will also be accepted. Each nomination must include a letter of nomination, the curriculum vita of the nominee, and a statement from the nominee that the nominee is willing to serve on the Panel under the conditions described in this notice and further specified in the Charter.

III. Copies of the Charter

To obtain a copy of the Panel's Charter, submit a written request to the DFO at the address provided or by e-mail at *APCPanel@cms.hhs.gov,* or call her at 410–786–4474. Copies of the