

or diagnostic information on individual children.

The purpose of this project is to: (1) Develop and pilot-test a scale to assess levels and sources of psychosocial stress in children who live in communities at or near hazardous waste sites; (2) modify the scale based on pilot-test results; (3) validate the scale on children living in communities near hazardous

waste sites; and (4) provide an evidence base for planning and conducting interventions in affected communities.

CDC will pilot test the scale on at least 50 children in two age groups (6th and 8th grade levels) at one or more test sites. Semi-structured interviews or focus groups will be conducted to determine whether additional variables need to be included in the scale. During

the second and third phases of the project, a scale will be used to screen up to 4,950 children in communities at or near hazardous waste sites. CDC plans to then use this data to create effective interventions methods to predict and explain levels of stress in children living around hazardous waste sites. The estimated annualized burden is 825 hours; there are no costs to respondents.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
Children 10–17 years old—Phase I	50	1	40/60
Children 10–17 years old—Phase II	200	1	20/60
Children 10–17 years old—Phase III	4,750	1	30/60

Dated: August 13, 2004.

Alvin Hall,

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

[FR Doc. 04–19424 Filed 8–24–04; 8:45 am]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fetal Alcohol Syndrome Prevention and Surveillance in South Africa: Developing Community-Level Strategies That Work

Announcement Type: New.

Funding Opportunity Number: RFA DD05–011.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: September 24, 2004.

Application Deadline: November 23, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 307, 317(C), and 317(k)(2) of the Public Health Service Act 42 U.S.C., Sections 241, 242 (I), 247b–4 and 247b (k) (2) as amended].

Purpose: The purpose of this program is to develop a model prevention program, successful in reducing hazardous alcohol use, reducing unintended pregnancies and/or promote pregnancy delay among childbearing age women at risk for an alcohol-exposed pregnancy in high risk communities (urban and rural) for Fetal Alcohol Syndrome (FAS) in South Africa. This program should be conducted in three stages.

Stage 1: The formative research state is composed of qualitative and quantitative research of knowledge, attitudes and practices in high risk women (women of child-bearing age at high risk of an alcohol-exposed pregnancy; women with children with FAS, spouses/partners, health care providers, obstetricians and nurses, specialty providers including alcohol treatment and substance abuse services, community leaders, etc.) regarding use of alcohol in pregnancy, use of contraception, knowledge of FAS, as well as issues such as identification of services and barriers to services. The formative research will describe the socio-demographic characteristics and attributes of the targeted community at risk, identify constraints and opportunities for behavior change, and allow the initiation and conduct of community and person-level interventions under stage 2.

Stage 2: The protocol and intervention development stage will use the information gathered in Stage 1 in combination with previous evidence-based research in FAS and HIV prevention in the U.S. and South Africa to develop a model intervention.

Stage 3: This stage will test the feasibility of the major components of the program in the high risk FAS communities targeted in this announcement.

The targeted communities should include geographic areas and/or selected subpopulations of childbearing-age women at high risk for an alcohol-exposed pregnancy in urban and rural areas of South Africa.

This program addresses the “Healthy People 2010” focus area of *Substance Abuse and Maternal, Infant, and Child Health*.

Measurable outcomes of the program will be in alignment with one (or more)

of the following performance goal(s) for the National Center on Birth Defects and Developmental Disabilities (NCBDDD): Prevent birth defects and developmental disabilities.

Research Objectives and Background: FAS is caused by maternal alcohol use during pregnancy and is one of the leading causes of preventable birth defects and disabilities. Recently, the highest prevalence of FAS worldwide was reported among children living in the winery area of the Western and Northern Cape region of South Africa with FAS prevalence rates ranging from 40.5 to 46.4 per 1,000 children. In the Gauteng region of South Africa (outside the wine-growing region) FAS prevalence rates range from 11.8 to 41.0 per 1,000 children. In addition, CDC has implemented a monitoring system in the area of De AAR, where the FAS prevalence rate was 80 per 1,000 live births. These rates show that FAS is a serious public health problem in some areas or subgroups of the South African population.

Important risk factors associated with heavy alcohol use among childbearing-age women include use of tobacco and other drugs, co-existing psychiatric conditions, history of sexual or physical abuse during childhood and/or adulthood, and a previous alcohol-exposed pregnancy. Studies have found that the strongest predictor of alcohol use during pregnancy is the level of alcohol use prior to pregnancy. Most of the same risk factors in women at risk of an alcohol-exposed pregnancy are also found in women at high risk for HIV infection.

Essential strategies for preventing alcohol-exposed pregnancies among high-risk women who are heavy alcohol users can include individual, group and community level interventions. Examples of individual level

interventions are: Provide one-on-one client services that offer counseling to reduce or abstain from alcohol intake, assist clients in assessing their own behavior and planning individual behavior change, support and sustain behavior change, and facilitate linkages to community health services (*i.e.*, alcohol treatment services) in support of behaviors and practices that prevent FAS. Such efforts must be coupled with strategies which address pregnancy postponement until the risk of prenatal alcohol use can be overcome. These approaches can be enhanced by developing local capacity through education and training of key public and private providers in the community.

Group level interventions shift the delivery of service from individual to groups of varying sizes. Group level interventions provide education and support in group settings to promote and reinforce safer behaviors and to provide interpersonal skills training in negotiating and sustaining appropriate behavior change to childbearing-age women at increased risk for FAS.

Community level interventions are directed at changing community norms, and increasing community support of the behaviors known to reduce the risk of FAS. Change in community attitudes, norms, and practices are brought about through health communication, social (prevention) marketing, community mobilization and organization, and community wide events.

Under identification of target population(s), applicants must identify urban and rural areas in which to conduct formative, epidemiologic, and intervention study activities. An entire province could be defined as a project geographical area or several regions or counties could be combined (containing both urban and rural populations) to establish the minimum eligibility criteria for FAS cases or childbearing-age women at risk. Applicants must be able to demonstrate that the area(s) selected include both urban and rural populations (within one defined geographical area or in two or more geographical areas with separate urban and rural populations).

In each case, the geographical area(s) selected must be representative of the country with at least 350,000 urban and rural childbearing-age women or a birth cohort of at least 25,000 births per year; and with high proportions of childbearing-age women at risk for an alcohol-exposed pregnancy [a minimum of 10 percent of non-pregnant, childbearing age women (aged 12–44 years) reporting frequent or binge drinking]; or a birth cohort with a minimum FAS prevalence rate of 10 per

1,000 live births; or communities with a high prevalence of HIV—due to the fact that FAS populations share common behavior patterns of substance abuse and sexual behavior; or by describing the high risk targeted population with relevant socio-demographic and epidemiological characteristics.

A woman who is at high risk for an alcohol-exposed pregnancy is one who engages in moderate (7–13 drinks per week) to heavy alcohol use (14 or more drinks per week) or binge drinking (4 or more drinks in a single occasion), is sexually active, and is not effectively practicing contraception.

The development of a model FAS prevention program for high risk communities in South Africa as specified in this announcement should include the aforementioned 3 stages.

Stage I: Formative research will be undertaken in the first year of the project, and should include conducting a community-based assessment to determine the women who are at highest risk within the community. This includes determining the characteristics of women at risk for an alcohol-exposed pregnancy, but not limited to those who have already had a child with FAS; and the risk characteristics of women at risk for HIV. Identification of environmental factors that could contribute to FAS; and potential venues for enrolling these populations for intervention services to prevent FAS will also be identified. This assessment could draw on existing data (through FAS surveillance systems) or on newly collected population-based data. Included within the scope of this work is conducting a needs assessment of health providers as to the services provided to the targeted populations including any perceived or real gaps between needs, expectations, and services delivered.

Stage II: The protocol and intervention development stage should be implemented during the first half of year two. Interventions should be developed to address the specific priority needs identified in Stage 1 including preparation of a study protocol to test the feasibility, acceptability, operational requirements of the interventions, and the development of an intervention evaluation plan including appropriate process and outcome measures. The protocol will include choices of sites, selection criteria for childbearing-age women at risk of an alcohol-exposed pregnancy, interventions and implementation methods, and the study evaluation. Piloting the protocol should be included in Stage II.

Stage III: The feasibility and evaluation stage is to be accomplished in the second half of year two and during year three of the project. It includes the implementation and evaluation of the model intervention(s) to assess whether the intervention can be appropriately utilized and replicated.

Activities: Awardee activities for this program are as follows:

1. Design an effective, innovative research approach that identifies and prioritizes key elements that are essential to community-based FAS prevention activities in the target populations.
2. Independent of the funding agency, develop a protocol to conduct community-based epidemiological and behavioral information gathering in childbearing age women populations that can include risky drinking behavior, sexual behavior patterns, social networks, substance abuse behavior, perceptions of social sexual norms, attitudes, self-efficacy, perception of current FAS prevention interventions, health-care and health-information seeking behaviors, and structural influences on behavior in order to determine the most appropriate intervention strategies to be used.
3. Identify, recruit, obtain informed consent forms and enroll and follow to completion participants as determined by the project-developed study protocol. Ensure that the protocol developed by the recipient details the study design, includes sample size calculations, denotes a study timeline, and conveys provisions to maintain confidentiality of study subjects.
4. Based on the recipient's independently developed protocol, assess maternal alcohol exposure through surveys and interviews with a sample of pregnant and non-pregnant women in the targeted population.
5. Perform tests as determined by the study protocol, and follow study participants over time as determined by the project-developed protocol.
6. Conduct needs assessment of health providers and other services provided to these populations. Determine the needs gap between the population and the services they receive.
7. Design and implement a provider education component for health personnel involved in intervention and surveillance and monitoring activities.
8. Develop and implement a feasibility protocol for prevention of FAS in a targeted geographic region as determined by the project that has increased rates of women at high risk for an alcohol-exposed pregnancy and/or increased rates of infants and children with FAS. Strengthen and improve

public health infrastructure to prevent FAS supporting additional services and links with existing, community-based programs that provide preventive health services.

9. Collect and evaluate information that could generate hypotheses about barriers to or opportunities for more efficacious innovations in FAS prevention including linkages with other populations at risk such as women at risk of HIV.

10. Collaborate with CDC as needed by requesting assistance in process and operational procedures.

11. Conduct project-developed research activities to answer specific research questions.

12. Provide appropriate privacy protections in accordance with the research protocol and informed consent stipulations for all participants.

13. Promote the peer-review of the study findings in the publication of study results.

14. Collect and analyze study data and prepare a final report of the outcomes of the study with recommendations for future research and prevention efforts.

CDC Responsibilities: In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. In this cooperative agreement, CDC Scientists (Scientific Liaisons) within the National Center on Birth Defects and Developmental Disabilities (NCBDDD) are an equal partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. These Scientific Liaisons will:

(1) Use their experience in studies of this nature to advise the project on specific questions regarding the project-developed protocol.

(2) As requested, assist the project in responding to inquiries regarding such areas as data management, data analysis, formats for presenting research findings, and in comparing project-developed evaluation formats with other research projects and activities known to CDC.

(3) Provide scientific consultation and technical assistance as requested on questions related to epidemiology, statistical and power calculations, and data storage and tracking formats used in other CDC sponsored research that could be advantageous to the project.

(4) Suggest to the project, upon request; processes for analysis, interpretation, and reporting of findings in the literature that can serve domestic and international scientific interests.

(5) In working with the selected foreign entity, provide technical

assistance and advice, and participate as an advisor in the collecting of information from the government's nationals.

CDC Scientific Program Administrator (SPA): The CDC NCBDDD will appoint an SPA, apart from the NCBDDD Scientific Liaisons who will:

(1) Serve as the Program Official for the funded research institutions.

(2) Carry out continuous review of all activities to ensure objectives are being met.

(3) Attend Coordination Committee meetings for purposes of assessing overall progress and for program evaluation purposes.

(4) Provide scientific consultation and technical assistance in the conduct of the project as requested.

(5) Conduct site visits to recipient institutions to determine the adequacy of the research and to monitor performance against approved project objectives.

Collaborative Responsibilities: The planning and implementation of the cooperative aspects of the study will be effected by a Coordination Committee consisting of the Principal Investigator from the participating institution and the CDC Scientific Liaisons. This Coordinating Committee will formulate a plan for cooperative research.

At periodic coordination committee meetings, the group will: (1) Make recommendations on the study protocol and data collection approaches; (2) discuss the target populations that have been or will be recruited; (3) identify and recommend solutions to unexpected study problems; and (4) discuss ways to efficiently coordinate study activities and best practices.

II. Award Information

Type of Award: Cooperative Agreement

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

Mechanism of Support: U84.

Fiscal Year Funds: 2005.

Approximate Total Funding: \$300,000 (The estimated funding amount is pending availability of FY 2005 funds, and is subject to change.)

Approximate Number of Awards: One.

Approximate Average Award: \$300,000. This amount is for the first 12-month budget period, and includes both direct and indirect costs.

Floor of Award Range: \$285,000.

Ceiling of Award Range: \$315,000. If you request a funding amount greater than the upper threshold, your application will not be eligible for review. You will be notified that you did not meet the submission requirements.

Anticipated Award Date: June 1, 2005.

Budget Period Length: 12 months.

Project Period Length: Four 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: Support will be provided only to non-profit NGOs or Universities in South Africa that can perform this activity. Applicants must identify and document their capacity to address urban and rural populations and meet the required volume of childbearing age women or birth cohort size, and the proportions of childbearing age women at risk or a birth cohort with a minimum FAS prevalence rate or communities with high HIV prevalence or the high risk targeted populations noted under the "Identification of Target Populations" discussion in this announcement. Providing precise information as to how these requirements will be met is essential to the consideration of your application for review.

III.2. Cost Sharing or Matching: Matching funds are not required for this program.

III.3. Other Eligibility Requirements: If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Applicants must document their present infrastructure, capacity, expertise, and experience (within organization or within organizations of collaborators) in conducting research directly related to the awardee activities cited in this announcement. Applicants must provide specific evidence to substantiate this capacity, experience, and expertise. Through documentation of a maximum of three pages in length, applicants must demonstrate that they can fully meet all eligibility criteria in order to be considered for formal review, and that they can conduct all project operations as noted under the listed stages for this program. This information must be included as part of the application and inserted immediately after the Face Page of the application.

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 under-represented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

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.

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:

Letter of Intent (LOI): The LOI must be written in the following format:

- Maximum number of pages: Two.
- Font size: 12-point unredlined.
- Paper size: 8.5 by 11 inches.
- Page margin size: One-inch margins.

- Printed only on one side of page.
- Single spaced.
- Written in English; avoid jargon.

The LOI must contain the following information: Name, address, and telephone number of the proposed Principal Investigator, number and title of this program announcement, names of other key personnel, designations of collaborating institutions and entities, and an outline of the proposed work, recruitment approach, and expected outcomes.

Application: Follow the PHS 398 application instructions for content and formatting of your application. 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/pubcommnt.htm>.

This announcement uses the non-modular budgeting format. The PHS 398 grant application form requires the applicant to enter the project title on page 1 (Form AA, "Face Page") and the project description (abstract on page 2).

The main body of the application narrative should not exceed 25 single-spaced pages. This narrative research plan should address activities to be conducted over the entire project period.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information may include curriculum vitae and resumes for key project staff, organizational charts, letters of commitment and support, graphic work plan with time intervals related to goals and objectives, etc.; and should be limited to those items relevant to the requirements of this announcement. Applicants must provide a graphic work plan that outlines major goals and objectives with timelines established for each calendar quarter covering the entire project period.

All material must be typewritten, with 10 characters per inch type (12 point) on 8½ by 11 inch white paper with one inch margins, no headers or footers (except for applicant-produced forms such as organizational charts, c. vitae, graphs and tables, etc.). Applications must be held together only by rubber bands or metal clips, and not bound together in anyway (including attachments/appendices).

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 Time:

Letter of Intent (LOI) Deadline Date: September 24, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and will allow CDC to plan the application review.

Application Deadline Date: November 23, 2004.

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 send your application by the appropriate postal service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application 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 carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on LOI and Application 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 your application 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 LOI or 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: Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions:

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

- Project funds cannot be used to supplant other available applicant or collaborating agency funds for construction or for lease or purchase of facilities or space.
- 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.

- If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement must be less than 12 months from the application due date.

IV.6. Other Submission Requirements:

LOI Submission Address: Lisa T. Garbarino, Public Health Analyst
National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, Mailstop E-87, Atlanta, Georgia 30333, United States of America, e-mail address: lgt1@cdc.gov.

Application Submission Address:
Submit the original and one hard copy of your application by mail or express delivery service to: Technical Information Management—RFA DD05-011, Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341, United States of America.

Applications may not be submitted by fax or e-mail at this time.

At the time of submission, four additional copies of the application, and all appendices must be sent to: Lisa T. Garbarino, Public Health Analyst, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, Mailstop E-87, Atlanta, Georgia 30333, United States of America, e-mail address: lgt1@cdc.gov.

V. Application Review Information

V.1. Criteria: You are required to provide measures of outcome and effectiveness that will demonstrate the accomplishment of the various identified objectives for each stage 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 the applications' overall score, weighting them as appropriate for each 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.

Under the evaluation criteria noted below, applicants must describe how they will address the program components as they relate to the Purpose and Research Objectives, and Recipient Activities as cited in this Announcement.

Your application will be evaluated against the following criteria:

1. Resources and Organizational Capacity:

- Does the applicant have experience, within its organization or the organization of partners to meet all the requirements of this announcement?
- Does the applicant have an existing infrastructure, within its organization or the organization of partners, sufficient to carry out the screening and follow-up in the proposal?
- Does the applicant have the ability to promptly assemble an effective team with the experience and time

commitments to promote full attention to the planning, implementation and evaluation of the project?

- Does the applicant, together with its partner organizations, have the capability to conduct the project, taking into account its institutional experience and current activities related to FAS?

- Does the applicant have the capacity to provide effective organizational collaborations, partnerships and formal agreements (including contractual), enabling the applicant to meet all project implementation and operational requirements?

2. Methods and Activities:

- Do the proposed methods and activities convincingly and comprehensively meet the intention of the announcement?

- Is the overall plan for planning, implementation and evaluation comprehensive and appropriate to accomplish the stated goals and objectives?

- Are methods and activities feasible within programmatic and fiscal restrictions?

- Will the methods and activities produce accurate, valid and reliable data?

- Are the calculated statistical power and the potential capacity of the research design adequate to generate meaningful results during the study period?

- Can the design be easily replicated for future use by sponsoring organizations and entities and an adequate plan presented for the dissemination of findings and recommendations for the benefit of other public health agencies?

- Does the applicant have a plan that will assure the privacy of all data collected, and that the identity of all participants will be protected from disclosure as specified through the project protocol and informed consent process?

3. Management, Staffing, and Objectives:

- Does the applicant have sufficient scientific resources for project planning and data management/analysis within the applicant's organization or through collaboration with universities or other agencies?

- Are the proposed staffing, staff qualifications and experience, and project organization sufficient to accomplish the objectives of the program?

- Does the proposed management and staffing include the specified tasks and responsibilities to be assigned for key positions proposed for financial

assistance, and for other personnel contributing to the project?

- Are the project goals and objectives relevant, specific, achievable, and measurable and can they be addressed through the proposed methods and within the proposed timeline?

4. Evaluation Plan:

- Have the evaluation components described in the announcement been addressed in the proposal?

- Are measurable objectives included in the proposal, and are the methods proposed appropriate for the measurable objectives?

- Does the evaluation plan include a process for overall evaluation of sub-components and the entire project, including the assignment of responsibility for ongoing review of specified components?

5. Budget Description and Justification: This includes the comprehensiveness and adequacy of the proposed budget in relation to program operations, collaborations, and services; and the extent to which the budget is reasonable, clearly justified, accurate, and consistent with the purposes of this research.

6. Protections: Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? This criteria will not be 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.

7. Inclusion: Does the application adequately address the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

- a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

- b. The proposed justification when representation is limited or absent.

- c. A statement as to whether the design of the study is adequate to measure differences when warranted.

- d. 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.

V.2. Review and Selection Process:

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness by NCBDDD. Incomplete applications and applications that are non-responsive as to the eligibility criteria and other eligibility requirements will not advance through the review process. Applicants will be

notified that their application did not meet submission requirements and will not receive further consideration.

Applications, which are complete and responsive, will be subjected to a preliminary evaluation (triage) by the scientific review group (Special Emphasis Panel—SEP) composed of external (non-CDC) peer reviewers to determine if the application is of sufficient technical and scientific merit to warrant further review by the SEP. Applications that are determined to be non-competitive will not be considered. Subsequent to the review meeting CDC will notify the investigator/program director and the official signing for the applicant organization of that determination.

Applications determined to be competitive will then be reviewed and scored under the formal SEP peer review process. The review of these fully competitive applications will result in the determination of the score and ranking for those applications.

Subsequent to the formal peer review by the SEP, a second level of review will be conducted by senior CDC program staff. This review is not intended to revisit the scientific merit of the applications. It is designed to review and discuss issues related to the adequacy and justification of the proposed budgets and funding ceilings, and to review the overall rating and ranking of all recommended applications. This will be done in order to prepare recommendations for funding based on the scientific merit as determined by the SEP; and to ensure that the recommendations are consistent and compatible with the Review and Selection section of the original program announcement.

V.3. *Anticipated Award Date:* June 1, 2005.

VI. Award Administration Information

VI.1. *Award Notices:* If your application is to be funded, you will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA 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 Requirement 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 Systems Requirements
- AR-15 Proof of Non-Profit Status
- AR-22 Research Integrity
- 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 Requirements:* You must provide CDC with an original, plus two copies of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925-0001, rev. 5/2001), on a date to be determined for your project for each subsequent budget year. The progress report will serve as your non-competing continuation application, and must contain the following elements:

- a. Current Budget Period Activities and Objectives.
- b. Current Budget Period Financial Progress.
- c. New Budget Period Program Proposed Activities and
- d. Objectives.
- e. Budget.
- f. Additional Requested Information.
- g. Measures of Effectiveness.

2. Financial status report and annual 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 sent 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 (PGO-TIM), CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341, United States of America, Telephone: (770) 488-2700.

For program technical assistance, contact: Lisa T. Garbarino, Public Health Analyst, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, Mailstop E-87, Atlanta, Georgia 30333, United States of America, e-Mail Address: lgt1@cdc.gov, Telephone: (404) 498-3979.

For budget assistance, contact: Vincent Falzone, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341, United States of America, Telephone: (770) 488-2763, e-mail: Vfalzone@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."

Dated: August 19, 2004.

William P. Nichols,

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

[FR Doc. 04-19425 Filed 8-24-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps.

Dates and Times: September 19, 2004, 12 p.m.-7 p.m.; September 20, 2004, 8:30 a.m.-5 p.m.; September 21, 2004, 9 a.m.-5:30 p.m.; September 22, 2004, 8 a.m.-10:30 a.m.

Place: Radisson Miyako Hotel, 1625 Post Street, San Francisco, California 94115-3603, (415) 922-3200.

Status: The meeting will be open to the public.

Agenda: The Council will be meeting in San Francisco, CA, in conjunction with the National Association of Community Health Care Centers. Members will have the opportunity to meet with community health care center administrators around issues of increased utilization of the National Health Service Corps programs and projections for workforce demands.

FOR FURTHER INFORMATION CONTACT: Tira Robinson-Patterson, Division of National Health Service Corps, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 8A-55, Rockville, MD 20857, telephone (301) 594-4140.

Dated: August 19, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-19489 Filed 8-24-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

[CIS No. 2324-04]

Termination and Re-Designation of Liberia for Temporary Protected Status

AGENCY: Department of Homeland Security, Bureau of Citizenship and Immigration Services.

ACTION: Notice.

SUMMARY: The Temporary Protected Status (TPS) designation of Liberia will expire on October 1, 2004. This notice terminates the current designation of Liberia and re-designates Liberia for TPS. The Attorney General designated Liberia for TPS on October 1, 2002. The Secretary of the Department of Homeland Security (DHS) had extended Liberia TPS through October 1, 2004. After reviewing conditions in Liberia, the Secretary of DHS finds that, while the armed conflict has ended, there are extraordinary and temporary conditions that prevent the safe return of nationals to Liberia. The re-designation will allow nationals of Liberia who have been continuously physically present in the United States since August 25, 2004, and continuously resided in the United States since October 1, 2002, to apply for TPS. This notice also sets forth procedures necessary for nationals of Liberia (or aliens having no nationality who last habitually resided in Liberia) to register for TPS. All current Liberia TPS beneficiaries who wish to continue to receive TPS benefits will have to register for TPS according to the procedures set forth in this notice.

EFFECTIVE DATE: The re-designation of Liberia's TPS designation is effective October 1, 2004, and will remain in effect until October 1, 2005. The registration period begins August 25, 2004, and will remain in effect until February 21, 2005.

FOR FURTHER INFORMATION CONTACT: Colleen Cook, Residence and Status Services, Office of Programs and Regulations Development, Bureau of Citizenship and Immigration Services, Department of Homeland Security, 111 Massachusetts Avenue, NW., 3rd Floor, Washington, DC 20529, telephone (202) 514-4754.

SUPPLEMENTARY INFORMATION:

What Authority Does the Secretary of the Department of Homeland Security Have To Terminate the Designation of Liberia and Re-Designate Liberia Under the TPS Program?

On March 1, 2003, the functions of the Immigration and Naturalization Service (Service) transferred from the Department of Justice to the Department of Homeland Security (DHS) pursuant to the Homeland Security Act of 2002, Public Law 107-296. The responsibilities for administering the TPS program held by the Service were transferred to the Bureau of Citizenship and Immigration Services (BCIS).

Under section 244 of the Immigration and Nationality Act (Act), 8 U.S.C. 1254a, the Secretary of DHS, after consultation with appropriate agencies of the Government, is authorized to designate a foreign state (or part thereof) for TPS. The Secretary of DHS may grant TPS to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in that state).

Section 244(b)(3)(A) of the Act requires the Secretary of DHS to review, at least 60 days before the end of the TPS designation or any extension thereof, the conditions in a foreign state designated under the TPS program to determine whether the conditions for a TPS designation continue to be met and, if so, the length of an extension of TPS. 8 U.S.C. 1254a(b)(3)(A). If the Secretary of DHS determines that the foreign state no longer meets the conditions for TPS designation, he shall terminate the designation, as provided in section 244(b)(3)(B) of the Act. 8 U.S.C. 1254a(b)(3)(B). Finally, if the Secretary of DHS does not determine that a foreign state (or part thereof) no longer meets the conditions for designation at least 60 days before the designation or extension is due to expire, section 244(b)(3)(C) of the Act provides for an automatic extension of TPS for an additional period of 6 months (or, in the discretion of the Secretary of DHS, a period of 12 or 18 months). 8 U.S.C. 1254a(b)(3)(C).