

## G. Evaluation Criteria

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

### 1. Experience in Environmental Justice—35 Percent

The applicant can clearly demonstrate (a) a track record in conducting environmental justice projects and activities with affected communities, and (b) the ability to collaborate with other HBCUs and HSIs to develop and implement a nationwide environmental justice program.

### 2. Scientific and Technical Merit of Proposed Program—25 Percent

The extent to which the applicant's proposal addresses (a) the scientific merit of the proposed project, including approach, feasibility, adequacy, and rationale of the design; (b) the technical merit of the proposed project, including the degree to which the project can be expected to yield results that meet the program objectives and the technical merit of the methods and procedures for the proposed project; and (c) the proposed project schedule, including clearly established project objectives for which progress toward attainment can and will be measured.

### 3. Program Personnel—25 Percent

The extent to which the proposal has described the (a) qualifications, experience, and commitment of the principal investigator (or project director) and his/her ability to devote adequate time and effort to provide effective leadership, and (b) the competence of associates to accomplish the proposed activity and their commitment and time they will devote.

### 4. Applicant Capability—15 Percent

Description of the adequacy and commitment of institutional resources to administer the program and the adequacy of the facilities as they impact on performance of the proposed activity.

### 5. Budget—(Not Scored)

The extent to which the budget is reasonable, clearly justified, and consistent with intended use of cooperative agreement funds.

## H. Other Requirements

### Technical Reporting Requirements

Provide original plus two copies of

1. Semiannual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period; and

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

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

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

AR-7 Executive Order 12372

AR-8 Public Health System Reporting Requirements

5R-9 Paperwork Reduction Act Requirements

AR-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2000

AR-12 Lobbying Restrictions

AR-18 Cost Recovery—ATSDR

AR-19 Third Party Agreements—ATSDR

AR-20 Conference Support

### I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 104(i)(14), and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9604 (i)(14), and (15)). The Catalog of Federal Domestic Assistance number is 93.161.

### J. Where To Obtain Additional Information

A complete copy of the announcement may be downloaded from CDC's home page on the Internet at: <http://www.cdc.gov> (click on funding).

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest (Announcement 99068). You will receive a complete program description, information on application procedures and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Nelda Godfrey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99068, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341-4146, Telephone:

(770) 488-2722, Email address: [nag9@cdc.gov](mailto:nag9@cdc.gov).

For program technical assistance, contact: Peter Sherman, Minority Health Program Manager, Agency for Toxic Substances and Disease Registry 1600 Clifton Road, NE (E-28), Atlanta, GA 30333, Telephone: (404) 639-5060, Email address: [pds2@cdc.gov](mailto:pds2@cdc.gov)

Dated: May 18, 1999.

**Georgi Jones,**

Director, Office of Policy and External Affairs  
Agency for Toxic Substances and Disease Registry.

[FR Doc. 99-12997 Filed 5-21-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 99102]

### Interventional Epidemiologic Research Studies of HIV/AIDS Among Pregnant Women, Children, and Adolescents; Availability of Funds

#### A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for new and competitive continuation cooperative agreements for interventional epidemiologic research studies of HIV/AIDS among pregnant women, children, and adolescents. This program addresses the "Healthy People 2000" priority areas of HIV Infection and Maternal and Infant Health. The purpose of the program is to support researchers in the conduct of HIV interventional epidemiologic research studies that foster prevention of HIV infection or HIV-related disease in infants, children, and adolescents. These include studies that address: (I) Mother infant rapid intervention at delivery (MIRIAD), (II) follow-up of perinatally HIV-infected children, and (III) parent communication training interventions with longitudinal follow-up among populations of color at high risk for infection for sexually transmitted diseases (STD) including HIV.

#### Research Studies

##### (I) Mother Infant Rapid Intervention at Delivery (MIRIAD)

Most HIV-infected pregnant women in the United States use hospitals for delivery, providing a crucial opportunity for systematic screening and intervention when indicated. In

some parts of the country, more infants might be spared HIV infection if the benefits of intrapartum/neonatal zidovudine (ZDV) were extended to pregnant women with little or no prenatal care than if transmission rates were further reduced among cohorts already receiving standard ACTG-076 therapy.

The MIRIAD Project should assess (1) a 24-hour counseling and voluntary rapid HIV testing program among women in labor presenting with unknown HIV status; (2) the feasibility of obtaining informed consent during labor (or, if not feasible, soon after birth); (3) reasons for lack of prenatal care among these women; (4) the rapid implementation and assessment of antiretroviral therapy—mono therapy or more intensive regimens—given at labor and delivery or to the neonate; (5) adherence to neonatal therapy; and (6) subsequent receipt of antiretroviral treatment and other services for women identified as HIV infected.

Innovative implementation strategies for the prevention of perinatal HIV transmission in settings where many HIV-infected women continue to receive little or no prenatal care are encouraged. Novel approaches for rapid bedside testing of women in labor and post-test counseling and referral/connection to care for HIV positive women and their infants should be carefully piloted at each site during the first 12–18 months of the funding period. A sustainable full-time in-labor (or, if not feasible, postpartum) counseling, testing and ZDV chemoprophylaxis intervention program should be instituted according to the standard of care at each participating site no later than 18 months into the funding period. Late-registrant mothers presenting after 36 weeks of pregnancy with unknown HIV status should also be offered rapid HIV testing and antiretroviral therapy during late pregnancy, intrapartum and to the neonate.

Administration of intravenous ZDV intrapartum (if possible) and oral ZDV to the neonate as soon as possible and within 48 hours of birth should be recommended as the minimum standard of perinatal HIV preventive care for HIV-infected women presenting in labor. More intensive antiretroviral therapy such as combination therapy should be presented as an option with possible post exposure prophylaxis benefit over mono therapy. Perinatal HIV transmission risk associated with various components of the antiretroviral intervention (e.g., neonatal only administration versus intrapartum + neonatal) will be compared while attempting to control for possible

confounders. Results from these studies should facilitate recommendations and provide effectiveness and operational research data on rapid HIV testing and administration of antiretrovirals among late-registrant women presenting in delivery rooms with unknown HIV status.

At each Project site, it is expected that a minimum of 1000 women will receive rapid HIV testing and counseling per year; and that a minimum of 20 HIV positive mother-infant pairs will be identified (after 36 weeks of pregnancy, during labor or within 48 hours after birth) and enrolled in MIRIAD annually. In order to reach these numbers and serve a large, population-based sample of disadvantaged women with high HIV sero prevalence and inadequate prenatal care, primary project sites are encouraged to collaborate with 2–3 other hospitals or maternity clinics within their geographic area. In the second and third year of the project, based on experience gained from the MIRIAD project, funded sites will be asked to develop outreach programs to assist other hospitals in their area implement rapid counseling and HIV testing at labor, and delivery of peripartum antiretroviral interventions.

Rapid testing for HIV during the peripartum period has the potential to improve clinical outcomes for both women and their infants but the question of how best to provide rapid HIV testing, how to perform urgent confirmatory testing in this setting, and how to best present women with risk/benefit information and treatment options needs systematic research. Integration of behavioral (i.e., to assess factors related to lack of prenatal care, counseling and testing in the delivery setting, informed consent issues, adherence to antiretroviral therapy in the neonatal period, enhancement of social support mechanisms) and biomedical sciences and a multi disciplinary research team is strongly encouraged.

## *II. Follow-up of Perinatally HIV-Infected Children*

Competing continuation applications are invited for the continued prospective follow-up of HIV-infected children enrolled in the Perinatal AIDS Collaborative Transmission Study (PACTS) between 1986 and 1998. Continued research areas of interest should include identifying maternal and early infant markers of rapid versus chronic pediatric disease progression, investigating host-related genetic factors related to disease progression, and assessing adherence and responses to the newest therapeutic interventions. As

this unique and well-characterized cohort of HIV-infected children ages into adolescence, opportunities will arise for in-depth analysis of the interrelationships among psycho social factors, pubertal development, and disease progression, as well as for research into behavioral interventions to prevent sexual HIV transmission.

This continuation project will support ongoing data collection and analysis for the HIV-infected children and up to two comparison groups: an HIV exposed but uninfected group (1:1 ratio matched for gender, site and closest in birth date to infected child) originally followed in PACTS, and a newly HIV-infected comparison group of children and adolescents, to compare psycho social development of perinatally infected children to these other groups. Follow-up should be done at least every 6 months, and include at a minimum: (1) Information on HIV-related clinical conditions, HIV-related medication use/adherence, hospitalizations, and survival; (2) all data points available from charts on viral load testing and lymphocyte immuno phenotyping as part of treatment protocols or clinical care; (3) storage of blood specimens for other HIV-related testing; (4) data on growth, pubertal development, neurocognitive functioning, and quality of life; and (5) data on school related outcomes such as grade failure, receipt of specific special services, and any available results of school achievement or developmental testing.

## *III. Parent Communication Training Interventions With Longitudinal Follow-up Among Populations of Color at High Risk for Infection for STD's Including HIV*

HIV Prevention messages must reach individuals early in life when healthy attitudes are still developing which most likely will lead to lifelong behavioral practices. Parents are in a unique and powerful position to shape young people's attitudes, values, and behaviors, and to socialize them to become healthy adults. Recent research suggests that giving parents information and communication skills about sexuality and HIV risk can be an effective HIV/AIDS prevention strategy. Applications are invited to conduct randomized intervention trials of parent communication training interventions with longitudinal follow-up among populations of color at high risk for infection for STD's including HIV. The intent is to examine the impact of a parental communication training program (i.e., minimal, basic, enhanced skills training) on parents' communication with their children and

the subsequent attitudes, beliefs and behaviors about sex and drug use of their children over time.

### B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

For the MIRIAD study, only institutions serving disadvantaged communities with high HIV seroprevalence among women of childbearing age (i.e., approximately 1 percent prevalence or higher) and the ability to recruit and retain a minimum of 20 HIV-infected pregnant women per year not receiving prenatal care or with unknown HIV serostatus before 36 weeks are invited to participate in this study.

**Note:** Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

### C. Availability of Funds

I. Approximately \$2.7 million is available in FY 1999 to fund approximately 5 to 6 awards for mother infant rapid intervention at delivery (MIRIAD). It is expected that the average award will be \$500,000, ranging from \$300,000 to \$700,000.

II. Approximately \$800,000 is available in FY 1999 to fund approximately 4 competitive continuation projects for follow-up of Perinatally HIV-infected children and a comparison group. It is expected that the average award will be \$200,000, ranging from \$150,000 to \$250,000.

III. Approximately \$900,000 is available in FY 1999 to fund approximately 3 awards for intervention trials of parent communication training. It is expected that the average award will be \$300,000, ranging from \$200,000 to \$400,000.

It is expected that all awards will begin on or about September 1, 1999, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change.

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

### Funding Preference

Preference will be given to achieve geographical diversity (e.g., Northeast, South, Central, and West).

For the Perinatally-HIV Infected Children Study, preference will be given to competing continuation applications from satisfactorily performing projects over applications for projects not already receiving support for follow-up of perinatally-HIV infected children.

### D. Program Requirements

In conducting activities to achieve the purpose of these programs, the recipient will be responsible for the activities listed under Recipient Activities and CDC will be responsible for conducting activities listed under CDC Activities:

#### 1. Recipient Activities

Recipients addressing the same research issue should be willing to participate in collaborative studies with other CDC-sponsored researchers, including using common data collection instruments, specimen collection protocols, and data management procedures, as determined in post-award grantee planning conferences. Recipients will be required to pool data for analysis and publication. Recipients are also required to work collaboratively as a study wide group to:

- a. Develop the research study protocols and standardized data collection forms across sites.
- b. Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants as determined by the study protocol and the program requirements.
- c. Continue to follow study participants as determined by the study protocol.
- d. Establish procedures to maintain the rights and confidentiality of all study participants.
- e. Perform laboratory tests (when appropriate) and data analysis as determined in the study protocol.
- f. Collaborate and share data and specimens (when appropriate) with other collaborators to answer specific research questions.
- g. Contribute blood specimens (at least every 6-12 months depending on the protocol requirements) for shipment and storage at a centralized repository system at CDC.
- h. Conduct data analysis with all collaborators as well as present and publish research findings.

#### 2. CDC Activities

- a. Provide technical assistance in the design and facilitate in the overall research project.

b. Facilitate and assist in the development of a research protocol for IRB (institutional review board) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Assist in designing a data management system.

d. Assist in performance of selected laboratory tests.

e. Work collaboratively with investigators to help coordinate research activities across sites involved in the same research project.

f. Assist in the analysis of research information and the presentation and publication of research findings.

### E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. Follow the directions for completing the application that are found in the Public Health Service (PHS) 398 kit.

### F. Submission and Deadline

Submit the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before July 19, 1999, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

**Deadline:** Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.) Applications which do not meet the criteria in (a) and (b) above will not be considered, and will be returned to the applicant.

### G. Evaluation Criteria

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

ranked on a scale of 100 maximum points according to the research area identified. All applicants must state which research category they are addressing.

#### *I. Mother Infant Rapid Intervention At Delivery (MIRIAD)*

##### 1. Recruitment, Retention and Adherence to Study Protocol (30 points).

a. Extent of applicant's experience in perinatal and pediatric HIV infection epidemiologic research.

b. Evidence of ability to successfully recruit and follow HIV-infected mothers and infants in longitudinal research studies.

c. Evidence of approximately 1% or greater HIV sero prevalence among pregnant women in the catchment area described in the application.

d. Ability to recruit and retain at least 20 and ideally over 30 HIV-infected pregnant women annually fulfilling the objectives of the MIRIAD study. Linkages with other area hospitals and a Community Advisory Board are strongly encouraged.

e. Ability to organize and provide a round-the-clock counseling and voluntary rapid HIV testing program among women in labor presenting with unknown HIV status; or immediately postpartum in first two days following delivery.

f. Evidence of ability to collect complete data including interviews of mothers in the immediate postpartum period and to obtain a sufficiently large blood sample from HIV-infected mothers enrolled in MIRIAD around the time of delivery.

g. Evidence of ability to collect complete data and to obtain regular blood samples from HIV-exposed infants, with at least one blood sample during the first 48 hours after birth.

h. Ability to oversee specimen collection for the timely processing, storage, and retrieval of laboratory specimens as needed for MIRIAD studies. This includes transfer of certain specimens to a central repository at CDC and transfer of other specimens to designated laboratories for specific laboratory studies.

i. Evidence of capability to address informed consent issues, enhance social support and foster adherence to the antiretroviral prophylaxis regimen, with special attention directed at adherence to the neonatal component of the regimen.

##### 2. Description and Justification of Research Plans (30 points).

a. Extent of familiarity and quality of experience pertinent to proposed research activities.

b. Understanding of the research objectives as evidenced by the high quality and scientific rigor of the proposed plan for research and a study design that is appropriate to answer research questions.

c. The inclusion of innovative approaches to investigate the feasibility of obtaining informed consent during labor for voluntary rapid HIV testing, rapid implementation of antiretroviral therapy given at labor and delivery or to the neonate, and adherence to neonatal antiretroviral therapy.

d. Extent to which the applicant demonstrates willingness to work with all successful applicants on development of a common core research protocol across funded sites.

e. Feasibility of plans to follow study participants. This includes demonstration of the experience of the investigator in following HIV-infected mothers and infants, and the comprehensiveness of the plan to protect the rights and confidentiality of all participants.

f. Thoroughness of plans for data management, data analysis, and laboratory analysis; reasonableness of data collected; and statistical rigor.

g. Extent to which proposal demonstrates feasible plans for coordinating research activities of multiple local clinical sites, where appropriate, and with CDC. Letters of support from cooperating organizations that demonstrate the nature and extent of such cooperation should be included.

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

(i) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation;

(ii) The proposed justification when representation is limited or absent;

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

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

##### 3. Research and Intervention Capability (20 points).

a. Applicant's ability to carry out the proposed research as demonstrated by the training and experience of the proposed research team and organizational setting, including demonstration of ability to collect, manage, and analyze accurate data in a timely manner.

b. Demonstration of working relationships with proposed investigators and extent to which services to be provided by external experts or consultants are documented by memoranda of agreement.

c. Demonstration of epidemiologic, behavioral, clinical, administrative, laboratory, data management and statistical analysis expertise needed to conduct proposed research.

##### 4. Staffing, Facilities and Time line (20 points).

a. Availability of qualified and experienced personnel with sufficient time dedicated to the proposed project.

b. Clarity of the described duties and responsibilities of project personnel.

c. Adequacy of plans for project oversight to assure quality of data.

d. Adequacy of facilities, equipment, data management resources, and systems for ensuring data security and patient confidentiality.

e. Adequacy of time line for completion of project activities.

##### 5. Other (not scored)

a. Budget: The extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

b. Human Subjects: Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

\_\_\_Yes \_\_\_No Comments:

#### *II. Follow-up of Perinatally HIV-Infected Children*

##### 1. Retention and Adherence to Study Protocol (20 points).

a. Extent of applicant's experience in perinatal and pediatric HIV infection epidemiologic research.

b. Evidence of ability to successfully follow HIV-infected children in longitudinal research studies.

c. Evidence of ability to collect complete clinical, laboratory and behavioral data and to obtain regular blood samples from HIV-infected children; and demonstration of capability to re-enroll and follow a 1:1 ratio of HIV exposed but uninfected children from the PACTS cohort originally followed at the site and/or a comparison group of newly HIV-infected children and adolescents.

##### 2. Description and Justification of Research Plans (30 points).

a. Extent of familiarity and quality of experience pertinent to proposed research activities.

b. Understanding of the research objectives as evidenced by the high quality of the proposed plan for research.

c. Originality of research, extent to which it does not replicate past or

present research efforts, and direct relevance of research to guiding current efforts to prevent HIV disease progression in children.

d. Feasibility of plans to follow study participants, and adequacy of sample size to address research questions. This includes demonstration of the experience of the investigator in following such persons, and the comprehensiveness of the plan to protect the rights and confidentiality of all participants.

e. Thoroughness of plans for data management, data analysis, and laboratory analysis; reasonableness of data collected; and statistical rigor.

f. Extent to which proposal demonstrates feasible plans for coordinating research activities across multiple clinical sites, where appropriate, and with CDC. Letters of support from cooperating organizations that demonstrate the nature and extent of such cooperation should be included.

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

(i) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation;

(ii) The proposed justification when representation is limited or absent;

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

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

### 3. Research Capability (30 points).

a. Applicant's ability to carry out the proposed research as demonstrated by the training and experience of the proposed research team, including demonstration of ability to collect, manage, and analyze accurate data in a timely manner.

b. Demonstration of working relationships with proposed investigators.

c. Demonstration of epidemiologic, behavioral, clinical, administrative, laboratory, data management and statistical analysis expertise needed to conduct proposed research.

### 4. Staffing, Facilities and Time Line (20 points).

a. Availability of qualified and experienced personnel, including individuals with biomedical, behavioral, and epidemiological expertise.

b. Clarity of the described duties and responsibilities of project personnel.

c. Adequacy of plans for project oversight to assure quality of data.

d. Adequacy of facilities, equipment, data management resources, and systems for ensuring data security and patient confidentiality.

e. Adequacy of time line for completion of project activities.

### 5. Other (not scored).

a. Budget: The extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

b. Human Subjects: Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

\_\_\_ Yes \_\_\_ No Comments:

### III. Parent Communication Training Interventions With Longitudinal Follow-up Among Populations of Color at High Risk for Infection for STD's Including HIV

#### 1. Description, Justification and Originality of Research Plans (25 points).

a. The inclusion of a detailed review of the scientific literature and theoretical underpinnings on which the proposed research plan and intervention are based. Application of science and theory to guide/justify the generation and articulation of specific research questions and hypotheses.

b. The originality of the proposed research and the extent to which it builds on old science, extends or creates new science and does not replicate past or present research efforts.

2. Familiarity with developmental and behavioral issues of children and families. Access and ability to recruit, retain, and conduct research with cohorts of 8 and 11 year old children and their families (25 points).

a. The inclusion of abstracts, presentations, and manuscripts that demonstrate the applicant's prior research expertise with children and families, with particular regard to family communication, family based interventions, and familial factors influencing risk taking behaviors.

b. Quality and description of methods used to identify, recruit, retain, and longitudinally follow cohorts of 8 and 11 year old children and their families for 5 years, including the documented ability to recruit and retain adequate numbers of study participants.

c. Quality, diversity, and description of methods used to collect quantitative data during research, intervention, longitudinal tracking, and evaluation phases of the research study with

cohorts of 8 and 11 year old children and their families for 5 years.

d. The inclusion of abstracts, presentations, and manuscripts that demonstrate the applicants ability to conduct longitudinal research with children and families.

### 3. Intervention research plan (25 points).

a. Extent to which the proposed research design and methods are appropriate for an intervention trial responsive to this request, including randomization procedures, statistical power to detect hypothesized differences, primary (attitudinal, cognitive, behavioral and biological) and secondary (relevant mediating variables) outcome measures, the reliability and validity of measures that will be used, and procedures for maximizing external and internal validity (e.g., sampling strategies and retention procedures, respectively).

b. Appropriateness of description and justification of the proposed research hypotheses, intervention plan, and intervention outcome measures that will be addressed as part of the intervention trial.

c. Quality and scientific rigor of the research design, methods, hypotheses, plan, and outcome measures that will be employed in the intervention trial.

d. Extent to which the applicant demonstrates willingness to work with CDC staff and consultants on development of a common research and intervention protocol across sites.

e. Adequacy of procedures for obtaining informed consent and maintaining participant confidentiality.

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

(i) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation;

(ii) The proposed justification when representation is limited or absent;

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

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

### 4. Research and intervention capability (15 points).

a. Applicant's ability to carry out the proposed research as demonstrated by the training and experience of the proposed research team and organizational setting, including

demonstration of previous behavioral/clinical interventions carried out.

b. Ability of the applicant to conduct the proposed research as reflected in the training, research, and behavioral intervention experience of staff members.

c. Extent to which services to be provided by external experts, consultants, or collaborating agencies are documented by memoranda of agreement in the appendix.

5. Staffing, facilities, and time line (10 points).

a. Availability of qualified and experienced personnel with sufficient time dedicated to the proposed project. Presence of behavioral scientists in key leadership positions on the project.

b. Clarity of the described duties and responsibilities of project personnel.

c. Adequacy of the facilities, equipment, data management resources, and systems for ensuring data security.

d. Specificity and reasonableness of time line.

6. Other (not scored).

a. Budget: The extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

b. Human Subjects: Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

\_\_\_Yes \_\_\_No Comments:

## H. Other Requirements

### Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Annual progress report;  
2. Financial status report, no more than 90 days after the end of the budget period; and

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

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

The following additional requirements are applicable to this program. For a complete description of each, see the document entitled "Descriptions of Other Requirements" in the GMB homepage under Program Announcements.

AR-1 Human Subjects Requirements.

AR-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.

AR-4 HIV/AIDS Confidentiality Provisions.

AR-5 HIV Program Review Panel Requirements.

AR-6 Patient Care

AR-7 Executive Order 12372 Review

AR-8 Public Health System Reporting Requirements

AR-9 Paperwork Reduction Act Requirements

R-10 Smoke-Free Workplace Requirements

AR-11 Healthy People 2000

AR-12 Lobbying Restrictions

## I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317 (k)(2) of the Public Health Service Act, (42 U.S.C. 241(a) and 247(k) (2)), as amended. The Catalog of Federal Domestic Assistance number is 93.943.

## J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Curtis Meusel, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99102, Centers for Disease Control and Prevention (CDC), Colgate Building Room 3000, 2920 Brandywine Road, M/S E-15, Atlanta, GA 30341, Telephone (770) 488-2738, Email address ctm6@cdc.gov.

For program technical assistance, contact: Jeff Efird, MPA, Deputy Chief, Epidemiology Branch, Division of HIV/AIDS Prevention Surveillance & Epidemiology, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E-45 Atlanta, Georgia 30333, Telephone (404) 639-6130, E-mail jle1@cdc.gov.

See also the CDC home page on the Internet to view and download all CDC funding opportunities (i.e., program announcements) and applicable application forms: HTTP://WWW.CDC.GOV.

Eligible applicants are encouraged to call before developing and submitting their applications.

Dated: May 18, 1999.

**John L. Williams,**

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

[FR Doc. 99-12996 Filed 5-21-99; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Injury Research Grant Review Committee: Meeting

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

*Name:* Injury Research Grant Review Committee (IRGRC).

*Times and Dates:* 6:30 p.m.-9 p.m., June 5, 1999; 8 a.m.-4 p.m., June 6, 1999.

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

*Status:* Open: 6:30 p.m.-7 p.m., June 5, 1999; Closed: 7 p.m.-9 p.m., June 5, 1999, through 4 p.m., June 6, 1999.

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

*Matters To Be Discussed:* Agenda items include a budget update; announcement regarding recent grant awards; discussion of review procedures; future meeting dates; and review of grant applications.

Beginning at 7 p.m., June 5, through 4 p.m., June 6, the Committee will meet to conduct a review of grant applications. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463.

*Contact Person for More Information:* John F. Finklea, M.D., Acting Executive Secretary, IRGRC, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway, NE, M/S K58, Atlanta, Georgia 30341-3724, telephone 770/488-4330.

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

Dated: May 18, 1999.

**Carolyn J. Russell,**

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

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