

REQUEST FOR INITIAL PROPOSAL (RFIP) FOR AWARD OF A COOPERATIVE AGREEMENT

OVERVIEW INFORMATION

Funding Agency: U.S. Environmental Protection Agency

Laboratory: National Health and Environmental Effects Research Laboratory (NHEERL)

Division: Human Studies Division (HSD)

Funding Opportunity Title: Studies to Develop Screening Tools for Young Children at Risk for Environmentally Mediated Neurobehavioral Disorders

Announcement Type: Initial Announcement

Funding Opportunity Number: EPA/ORD/NHEERL/HSD-(04)-TBN17141

Catalog of Federal Domestic Assistance (CFDA) Number:
66.511 ORD Consolidated Research

Action Dates: RFIP issued: 3/24/04

Final date to submit technical questions: 4/23/04

Proposals due: 5/23/04

Executive Summary:

"EPA desires to support research to expand current understanding of the impact of environmental conditions on neurobehavioral development in humans. This project will extend previous work evaluating potential predictors of behavioral disorders usually diagnosed at the time of school entry or later. The aim is to uncover predictive indicators in existing records and then use those indicators to screen children at an early age. The assumption is that early detection of at risk children will allow time for intervention that will lessen or eliminate the negative developmental outcomes."

Anticipated Funding: \$120,000 - One award

Eligible Applicants: States, territories and possession, and Tribal nation of the United States, including the District of Columbia, for public and private State universities and colleges, hospitals, laboratories, State and local government departments, other public or private nonprofit institutions, and in some cases, individuals who have demonstrated unusually high scientific ability.

Point of Contact: Diane Pierce

Telephone: 919-966-0646

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FULL TEXT OF ANNOUNCEMENT

I. Funding Opportunity Description

Title of Assistance Opportunity: Studies to Develop Screening Tools for Young Children at Risk for Environmentally Mediated Neurobehavioral Disorders

Background:

"EPA desires to support research to expand current understanding of the impact of environmental conditions on neurobehavioral development in humans. This project will extend previous work evaluating potential predictors of behavioral disorders usually diagnosed at the time of school entry or later. The aim is to uncover predictive indicators in existing records and then use those indicators to screen children at an early age. The assumption is that early detection of at risk children will allow time for intervention that will lessen or eliminate the negative developmental outcomes.

Attention Deficit Hyperactivity Disorder (ADHD) is an increasingly diagnosed neurobehavioral condition that is speculated to be linked to environmental exposures. Agents in the environment that are proposed to be linked to ADHD include pesticides, industrial chemicals and metals. Potential exposure media include indoor air, ambient air and drinking water. To begin to assess this relationship, work was undertaken to obtain access to and review case records of ADHD patients. To date, approximately 400 case records from the Duke University Medical Center ADHD clinic have been reviewed with the focus on review of data related to pregnancy, birth, development, medical history and early temperament factors. A data base was developed to facilitate application of descriptive and exploratory statistical analysis techniques to characterize the data and evaluate potential predictive relationships among variables associated with early development and behavioral and diagnostic outcomes. The results of the analysis were used to develop supplemental screening questions to refine and extend the scope and predictive value of standard assessments.

This project will expand the scope of the current data base by increasing the number of cases, analyzing the expanded data base, comparing the findings of the original and expanded data base analysis, developing additional screening questions and validating the screening approach. In conducting activities to achieve the purpose of this program, the recipient shall be responsible for the Recipient Activities listed in the below Funding Priorities/Focus section.

A. Recipient Activities

Funding Priorities/Focus:

"The purpose of this RFIP is to solicit proposals for a cooperative agreement to carry out research to expand current understanding of the impact of environmental conditions on neurobehavioral development in humans. Specific examples of such activities are listed

below. Investigators responding to this RFIP, however, should not limit themselves to these activities.

1. Develop a study design and protocol.
2. Identify case records from a University or Hospital based ADHD Clinic.
3. Conduct a review of case records in accordance with the study design and protocol.
4. Enter data from case records into the existing data base.
5. Analyze data.
6. Refine and expand the existing set of screening questions.
7. Validate the screening approach in a general age matched sample and a clinic-based population.

GPRA Goals, Objectives:

The specific Government Performance Results Act (GPRA) Goals, Objectives and Sub-objectives that relate to this RFIP include:

GPRA Goal: 4 - Healthy Communities and Ecosystems

Objective(s): 05 - Science and Research: Human Health and Ecosystems

Sub-objective(s): F B2 D

Statutory Authority for Award of Assistance: This research is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act, Section 20 as Amended.

II. Award Information

Amount and Range of Individual Award: \$120,000

Number of Awards: One

Funding: The EPA is expected to fund this award over a period of three years. Funding of the first year of the award is expected to be at \$40,000. Additional funding of \$40,000 during the second year and \$40,000 during the third year will be contingent upon availability of funds and satisfactory progress by the selected recipient.

Project Period: (08/04 to 07/07)

Supplemental Applications: Applications for supplemental awards of existing EPA assistance agreements will not be eligible to compete for this assistance opportunity.

Type of Award: The Agency anticipates the award of a cooperative agreement.

Anticipated Federal Involvement:

EPA and the Project Officer for this assistance agreement anticipate substantial involvement in the implementation of the research as follows:

- "1. EPA is able to provide technical assistance in the design and conduct of the research including, but not limited to, the following:
 - a. providing technical consultation in the design and conduct of the project;
 - b. obtaining Office of Management and Budget clearance for the collection of data;
 - c. participating in analysis of research data and the interpretation and dissemination of research findings;
2. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all institutions participating in the research project. The EPA human subjects official will review and approve the protocol after review by all other participating institutions and on at least an annual basis until the project is completed.
3. Assist in the development of a Quality Assurance Project Plan (QAPP). The EPA will review and approve the QAPP. In addition, the recipient will be subject to Technical Systems Reviews (TSRs) which will be conducted by EPA staff. The recipient shall be responsible for responding to TSR reports."

III. Eligibility Information

Eligible Applicants: Programs under CFDA 66.511 are available to each State, territory and possession, and Tribal nation of the United States, including the District of Columbia, for public and private State universities and colleges, hospitals, laboratories, State and local government departments, and other public or private nonprofit institutions, and in some cases, individuals who have demonstrated unusually high scientific ability.

Cost Sharing Requirements: None.

Other Eligibility Criteria:

Eligible nonprofit organizations include any organizations that meet the definition of nonprofit in OMB Circular A-122. However, nonprofit organizations described in Section 501(c)(4) of the Internal Revenue Code that engage in lobbying activities as defined in Section 3 of the Lobbying Disclosure Act of 1995 are not eligible to apply. Universities and educational institutions must be subject to OMB Circular A-21.

Groups of two or more eligible applicants may choose to form a coalition and submit a single application for this assistance agreement. Coalitions must identify which eligible organization will be the recipient of the assistance agreement, and which eligible organizations(s) will be subawardees of the recipient. Sub awards must be consistent with the definition of that term in 40 CFR 30.2(ff). The recipient must administer the assistance agreement, is accountable to EPA for proper expenditure of the funds, and will be the point of contact for the coalition. As provided in 40 CFR 30.2(gg), sub recipients

are accountable to the recipient for proper use of EPA funding.

Coalitions may not include for profit organizations that will provide services or products to the successful applicant. For profit organizations are not eligible for sub awards. Any contracts for services or products funded with EPA financial assistance must be awarded under the competitive procurement procedures of 40 CFR Part 30. The regulations also contain limitations on consultant compensation. Applicants are not required to identify contractors or consultants in the proposal. Moreover, the fact a successful applicant has named a specific contractor or consultant in the proposal EPA approves does not relieve it of its obligations to comply with competitive procurement requirements or consultant compensation limitations.

Applications will be reviewed for eligibility during the Administrative Review and Relevance Review. These reviews may have the effect of making a proposal ineligible for award. The Administrative Review and Relevance Review factors are as follows:

Administrative Review: All initial proposals will be subject to an administrative review to ensure that they conform with the requirements of this RFIP. EPA may reject any application that fails to conform substantially with the requirements of this RFIP.

Relevance Review: Initial proposals that are found administratively acceptable will be subjected to a review for relevancy to EPA's mission to support advancement of environmental science. Initial proposals may be rejected if they are found to lack relevance. Examples include:

1. Proposal is deficient technically with no chance for consideration.
2. Proposal fails to advance the objectives stated in the solicitation even if successfully performed.
3. Proposal essentially duplicates research already completed or underway.
4. Proposal fails to demonstrate a public purpose of support and stimulation; i.e., it implies the primary purpose is to provide direct support to the Federal government.

Only initial proposals that meet the administrative review and relevance review will be subject to the technical review and be eligible for award. Initial proposals from ineligible applicants or proposals that failed to meet either the administrative review or the relevance review will be deemed ineligible for award and returned without further review.

IV. Application and Submission Information

Address to Request Application Package: Diane Pierce, US EPA, Human Studies Division, MD-58A, Research Triangle Park, NC 27711 or pierce.diane@epa.gov.

Application information is also available from the EPA/ORD/NHEERL website at <http://www.epa.gov/nheerl/about/researchopportunities.html>. under the heading Assistance Opportunities. This document, and any subsequent amendments, constitutes the entire Request for Initial Proposal.

Content and Form of Application Submission: At a minimum, the initial proposal shall consist of the following items:

1. A cover sheet that identifies the RFIP title and identification number, name and address of applicant, point of contact, telephone number, e-mail address for the applicant, applicant's DUNS number (see Section VIII), and the date of the submission.
2. Technical proposal that discusses the approach to accomplishing the goals stated under Funding Priorities/Focus, the capabilities (in terms of personnel and facilities) of the applicant to complete the research, the expected results from this research, how the research will advance and stimulate the public need, and how the results will be made available to the public and government. In addition, in developing the technical proposal, the applicant should focus on the evaluation criteria set forth in Section V and include in the proposal sufficient information to address each of the criteria in the order listed.

The page limitation of the technical proposal is 10 double sided pages (20 pages total) with a minimum font size of 12. This page limitation should include all text, tables, figures, references, attachments, and appendices. In addition, a 2-page curriculum vitae should be included for the principal investigator and any other key personnel identified in the proposal.

3. A budget estimate for the project that is broken down into direct labor, fringe benefits, equipment, travel, other direct costs and overhead with summaries for each year and the total for the entire project. Indicate any proposed cost sharing (not required).
4. A Quality Management Plan that describes the applicant's quality system for its organization. The Plan must be prepared in accordance with the specifications provided in *EPA Requirements for Quality Management Plans (QA/R-2)* or address the same topics as required by QA/R-2. QA/R-2 may be downloaded from the Internet at http://www.epa.gov/quality/qa_docs.html

Initial proposals should be submitted in the original with 3 copies and should be double-sided.

Submission Date, Time, and Location: To be considered timely, initial proposals must

be received by 4:00 pm local time on 5/23/04 from the U.S. Postal Service or other commercial delivery service. Proposals should be submitted to Diane Pierce, US Environmental Protection Agency, Human Studies Division, 104 Mason Farm Road, Chapel Hill, NC 27514-4512 . Initial proposals received after the deadline will not be considered and will be returned to the submitter. Applicants that submit proposals by hand should request a receipt from the security guard at the main entrance of the EPA facility.

Intergovernmental Review: This assistance opportunity is subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." Applicants should contact their State's Single Point of Contact (SPOC) to find out how to comply with the State's process. The names and addresses of the SPOC's are listed in the Office of Management and Budget's home page at: <http://www.whitehouse.gov/omb/grants/spoc.html>.

Funding Restrictions: Funding of the first year of the award is expected to be at \$40,000. Additional funding of \$80,000 will be contingent upon availability of funds and satisfactory performance during the first year.

Amendments: Amendments will be posted on this website and the due date for initial proposals will be extended if deemed appropriate.

Other Submission Requirements: None.

V. Application Review Information

Administrative Review: All initial proposals will be subject to an administrative review to ensure that they conform with the requirements of this RFIP. EPA may reject any application that fails to conform substantially with the requirements of this RFIP.

Relevance Review: Initial proposals that are found administratively acceptable will be subjected to a review for relevancy to EPA's mission to support advancement of environmental science. Initial proposals may be rejected if they are found to lack relevance. Examples include:

1. Proposal is deficient technically with no chance for consideration.
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Criteria:

Technical Review: Initial proposals that are found administratively acceptable and relevant shall be reviewed for technical merit against the following criteria.

- "1. Technical approach for addressing the RFIP focus including investigator proposed activities. (30%)
2. Qualification of the proposed key personnel. Applicants should identify key personnel qualifications and their proposed time commitment to this assistance agreement. (30%)
3. Institutional capability including laboratory space and equipment made available for this assistance agreement. (10%)
4. Past Performance. Demonstrated peer-reviewed publication record in projects of similar size, relevance and scope to this agreement. (25%)
5. Quality Management Plan. Current overall quality assurance plan for the applicant's organization. (5%)"

Review and Selection Process:

Evaluation Process: The administrative and relevancy reviews will be conducted by EPA personnel who are not a part of the technical review panel. The review of the technical criteria will be conducted by a technical review panel which shall consist of at least one internal EPA reviewer and at least two non-EPA reviewers who are able to demonstrate technical expertise in the areas related to the RFIP. In addition, the reviewers shall have no conflict of interest.

Source Selection: A preliminary selection of the applicant for award will be made based upon the rankings of the technical review panel and the other technical review factors. The technical review factors are: Technical approach, Qualification of the proposed key personnel, Institutional capability, Past Performance, and Quality Management Plan. The Decision Official is an Office of Research and Development (ORD) manager who will preliminarily select which applicant should receive the award.

Full Application: The applicant selected for award will be requested to submit a full, detailed application in accordance with the guidance provided by EPA's Office of Grants and Debarment (<http://www.epa.gov/ogd/>). For example, EPA will discuss significant comments received from the technical reviewers, aspects of the budget that may be

questionable, the proposed terms and conditions for the agreement, and the nature and extent of EPA collaboration.

Rejection Factors: Applications may be rejected because they fail to comply with the administrative requirements of the RFIP, they are found to lack relevancy, they are judged technically unacceptable, or they are not deemed suitable for award due to other factors (if identified). EPA reserves the right to reject all proposals or applications and make no award based on this RFIP.

Disputes: Disputes will be resolved pursuant to the process described in 40 CFR 30.63 and Part 31, subpart F.

Anticipated Announcement and Award Dates: The anticipated award date is 1/05.

VI. Award Administration Information

Award Notices: Notice of award will be made in writing by an official in the EPA Grants Administration Division. Preliminary selection by the Decision Official in the Office of Research and Development does not guarantee an award will be made. Applicants are cautioned that only a grants officer can bind the Government to the expenditure of funds. No commitment on the part of EPA should be inferred from technical or budgetary discussions with an EPA Program Official. A Principal Investigator or organization that makes financial or personnel commitments in the absence of a grant or cooperative agreement signed by the EPA Grants Award Official does so at their own risk.

EPA will promptly notify in writing (postal or email) those applicants whose initial proposal has not been selected for award. An unsuccessful applicant may request a debriefing to better understand the evaluated strengths and weaknesses of its proposal and the reasons it was not selected for award.

Administrative and National Policy Requirements:

Regulations and OMB Coverage:

Grants and agreements with institutions of higher education, hospitals, and other non-profit organizations are subject to 40 CFR Parts 30 and 40 and OMB Circular A-122 for non-profits and A-21 for institutions of higher learning.

Grants and agreements with state, local, and tribal governments are subject to 40 CFR Parts 31 and 40 and OMB Circular A-87.

Programmatic Terms and Conditions: Terms and conditions will be negotiated with the selected recipient covering the following requirements:

An acceptable quality assurance document, i.e., Quality Assurance Project Plan (QAPP), shall be due within 45 calendar days of award.

To further the assistance-agreement objectives of public support and stimulation, applicants must agree to make methods, models, and data resulting from this agreement accessible to the public and to EPA researchers.

Reporting:

Quarterly Progress Reports: The selected recipient will be required to submit quarterly progress reports summarizing technical progress, difficulties encountered, and planned activities for the next quarter. Each report shall include a summary of expenditures.

Final Report: The selected recipient will be required to submit a final report within 90 calendar days of the completion of the period of performance.

VII. Agency Contact

The primary agency contact for this RFIP is Diane Pierce at:

US Environmental Protection Agency
Human Studies Division
MD-58A
Research Triangle Park, NC 27711

Telephone: 919-966-0646
Telefax: 919-966-6212
E-mail: pierce.diane@epa.gov

If unable to reach Diane Pierce, contact Ms. Margaret Mann at:

Telephone: 919-541-4896
Telefax: 919-541-2581
E-mail: mann.margaret@epa.gov

VIII. Other Information

Questions: Questions regarding this RFIP should be submitted in writing by 4/23/04. Do not attempt to seek information regarding this RFIP from any source other than those identified in Section VII as the information may not be accurate. Questions that are considered significant will be answered via an amendment to this RFIP.

Confidential Information: Clearly mark information considered to be confidential. EPA will make final confidentially decisions in accordance with Agency regulations at 40 CFR, Part 2, Subpart B. As noted above, initial proposals for research and demonstration projects will be provided to at least two non-EPA consultants for technical review. All reviewers will be required to sign confidentiality agreements certifying they will keep all deliberations confidential, and they will not copy any portions of any material provided by EPA for review, and they will return all material to EPA upon request. If you are unwilling to allow non-EPA consultants to review your proposal, please advise us of your decision in a cover letter to your proposal.

DUNS Number: Grant applicants are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. OMB has determined that there is a need for improved statistical reporting of Federal grants and cooperative agreements. Use of the DUNS number government-wide will provide a means to identify entities receiving those awards and their business relationships. The identifier will be used for tracking purposes, and to validate address and point of contact information.

A DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (Grants.gov). The DUNS number will supplement other identifiers required by statute or regulation, such as tax identification numbers. Organizations can receive a DUNS number in one day, at no cost, by calling the dedicated toll-free DUNS Number request line at 1-866-705-5711. Individuals who would personally receive a grant or cooperative agreement award from the Federal government apart from any business or non-profit organization they may operate are exempt from this requirement. The website where an organization can obtain a DUNS number is: <http://www.dnb.com>. This takes 30 business days and there is no cost unless the organization requests expedited (1-day) processing, which includes a fee of \$40.