

**INVESTIGATION OF THE ASSOCIATIONS BETWEEN AIR POLLUTION AND HEALTH
USING ALTERNATIVE ESTIMATES OF HUMAN EXPOSURE**

General Information

Announcement Type: Initial Announcement
Funding Instrument Type: CA
Funding Opportunity Number: EPA-ORD-07-28347
Posted Date: November 14, 2007

Original Due Date for Applications: To be considered timely, printed hard-copy applications must be received by 3:00 p.m. local time in RTP, NC on January 30, 2008 from the U.S. Postal Service or other commercial delivery service. Applications submitted electronically through grants.gov must be received by grants.gov by 3:00 p.m. EDT on January 30, 2008.

Current Due Date for Applications: To be considered timely, printed hard-copy applications must be received by 3:00 p.m. local time in RTP, NC on January 30, 2008 from the U.S. Postal Service or other commercial delivery service. Applications submitted electronically through grants.gov must be received by grants.gov by 3:00 p.m. EDT on January 30, 2008

Archive Date: (To be completed by GIAMD)
Category of Funding Activity: Environment
Anticipated Number of Awards: 2
Anticipated Total Program Funding: \$400,000
Award Ceiling: \$200,000

Award Floor: \$100,000
CFDA Number: 66.511 ORD Consolidated Research

Cost Sharing or Matching Requirement: None
Geospatial Information: It is anticipated that the agreements that are awarded will involve or relate to geospatial 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. Profit-making firms are not eligible to receive awards. 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.

Federal Agency Name

U.S. Environmental Protection Agency, Office of Research and Development, National Exposure Research Laboratory, Immediate Office, Attn: Claudette Mitchell. (D305-01), Research Triangle Park, NC 27711

Description

The U.S Environmental Protection Agency (EPA) is seeking applications that propose development and evaluation of alternative human exposure indicators/estimates of PM (particulate matter), gaseous criteria pollutants (e.g. nitrogen dioxide, ozone), or air toxics (e.g., benzene, formaldehyde and other motor vehicle related volatile organic compounds) in the examination of the associations between outdoor air pollution and human health effects. The ultimate objective of this research is to demonstrate the utility of improving the exposure assignments made in the commonly performed epidemiologic studies of effects of ambient air pollution on human health. Adverse effects of air pollution on human health have been well documented since the London Fog episodes in the early 1950s. They include acute and chronic effects of both particulate and various gaseous air pollutants on morbidity and mortality (Pope et al. 2002; Pope and Dockery 2006; Dominici et al. 2006; Burnett et al. 2000; Kinney and Özkaynak 1991; Ito et al. 2005; Levy et al. 2005; Ware et al. 1993; Woodruff et al. 1998). The morbidity effects of air pollution range from decreased lung function to exacerbation of symptoms of asthma and chronic bronchitis to more serious cardiopulmonary events, such as increased hospitalizations or myocardial infarctions (Dominici et al. 2006; Gauderman et al. 2007; Schwartz 1999). Clearly, accurate assessment of personal exposures is a critical element of all environmental health studies. However, most air pollution epidemiology studies have traditionally relied upon imperfect surrogates of personal exposures, such as information based on readily available central-site outdoor concentration monitoring data in the absence of personal exposure measurements (Özkaynak et al. 2007; Özkaynak 1986). For instance, epidemiologic studies on PM and ozone and other gaseous criteria pollutants (e.g., nitrogen dioxide, carbon monoxide, sulfur dioxide) have used ambient monitoring data collected by regulatory or short duration research studies. In contrast to the criteria air pollutants, regulatory compliance monitoring for many of the air toxics have been quite limited, thus making it difficult to conduct an investigation of health effects due to either the short-or long-term exposures to air toxics of concern. Since individuals are exposed to both indoor and outdoor generated PM and other air pollutants during the course of a typical day (e.g., indoors and outdoors at residences, exposures while commuting, at school or workplace, etc.), it is important to determine the relative contributions of these pollutants in microenvironments of concern for each individual (Özkaynak et al. 1996; Kinney et al. 2002). In the context of air pollution exposure and health studies, researchers have now begun using a variety of space and time resolved atmospheric models and microenvironmental personal exposure modeling tools (Isakov and Özkaynak 2007, Burke et al. 2001; Özkaynak et al. 2007; Isakov et al. 2006). However, the types of information needed to run some of these exposure models can be high, including: time-activity and commuting information, micro environmental measurements of concentrations, air exchange and HVAC

information, housing and other physical factors information, and information on consumer product use. The goal of this research is to develop and apply innovative exposure estimates in the evaluation of health effects due to atmospheric particles and gases of health concern. The results obtained from appropriately designed and conducted epidemiologic studies help enhance public health by reducing uncertainties in exposure and risk assessments and by providing information that can be used to develop optimum exposure and risk mitigation strategies. The research supported under this solicitation will integrate advanced modeling approaches with available measurement data to strengthen the air quality and human exposure aspects of on-going or future epidemiologic studies.

Application Materials

You may submit either a printed application or an electronic application (but not both) for this announcement. The printed application must be submitted to Claudette Mitchell, US EPA, (D305-01) NERL/IO, Research Triangle Park, NC 27711 by the closing date and time. To apply electronically, the electronic application package available through the <http://www.grants.gov/> web site must be used. If your organization is not currently registered with Grants.gov, you need to allow approximately one week to complete the registration process. This registration, and electronic submission of your application, must be performed by an appropriate representative of your organization.

Agency Contact Person for Electronic Access Problem

Walter Stutts, phone: (513) 569-7487 email: stutts.walter@epa.gov

Link to Full Announcement

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FULL TEXT OF ANNOUNCEMENT

I. Funding Opportunity Description

Title of Assistance Opportunity: “INVESTIGATION OF THE ASSOCIATIONS BETWEEN AIR POLLUTION AND HEALTH USING ALTERNATIVE ESTIMATES OF HUMAN EXPOSURE”

Background

The mission of the U.S. Environmental Protection Agency (EPA) is to protect public health and safeguard the environment. Risk assessment and risk management are an integral part of this mission. EPA’s Office of Research and Development (ORD) Human Health Research Program has developed a strategic approach for research to improve human health risk assessment and risk management. The main objective of the program is to reduce uncertainties in the risk assessment process by providing a greater understanding of the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to environmental toxicants. Variability in exposures and how they relate to changes in concentrations of pollutants outdoors is a key uncertainty in human health risk assessments. Studies to understand the exposures of both susceptible and general populations to ambient air pollutants of health concern are an important research area for the Agency.

Since direct personal exposure measurements on all or most of the health study subjects cannot be practically obtained, it is important to consider various alternative surrogates or indicators of exposures -- ranging from simple to more complex, depending on the particulars of the epidemiologic study design and availability of exposure-related information. A number of different surrogates of personal exposures have been used in criteria air pollution epidemiology studies. The majority of these are based on available ambient monitoring data often collected for regulatory compliance purposes. Epidemiologists have used such data either directly or after applying GIS-based kriging or interpolation methods to approximate outdoor concentrations near study subjects residences or communities. A few studies have also incorporated results from atmospheric dispersion modeling applications in the analysis of health data (cf. Hoffman et al. 2007). More recently semi-empirical GIS-Based Land Use Regression (LUR) modeling methods have become popular in the analysis of cohort study health data. In addition to available spatially distributed data, these models incorporate landscape characteristics, such as proximity to roadways and other outdoor sources of air pollution near the homes of study subjects (English et al. 1999; Jerrett et al. 2005; Smith et al. 2006; Marshall et al. 2007; Arain et al. 2007). Other studies have indirectly incorporated indoor or personal exposure-related “effect modifiers” in the health effects models, such as information on housing type, age, use of combustion appliances indoors, presence or use of different types of air conditioning or heating sources, etc. However, in the context of air pollution studies, few if any studies have directly incorporated penetration of outdoor pollutants inside residences or into other key microenvironments (e.g., in-vehicles, inside offices, schools).

A number of publications have already shown the importance of exposure prediction errors in the interpretation of time-series epidemiology studies of PM mortality or morbidity effects (Zeger et al. 2000; Dominici et al. 2000; Zeka and Schwartz 2004). More recently, studies by Sarnat et al. 2006 and Jerrett et al. 2005 have also shown that more narrowly defining the geographic domain of the study populations analyzed and the corresponding ambient concentrations of selected air pollutants, leads to stronger or greater associations between PM or other ambient pollutants and either the hospital admissions or mortality. The impact of exposure misclassification or exposure prediction errors on the outcome of air pollution epidemiology studies varies, of course, depending on the particular study design. In general, the greater the (spatial inter- or intra- urban) scales are, the greater the likelihood these exposure predictions play an important role in the epidemiologic study results or in their interpretation. A number of alternative approaches are now available for improving the exposure predictions required by air pollution health studies.

Over the past decade or so, researchers at ORD's National Exposure Research Laboratory (NERL) have been developing measurement and modeling information that can be used to provide spatially and temporally resolved ambient, personal, and/or population exposures in support of exposure assessment for epidemiologic studies (cf. Isakov et al 2006; Isakov and Özkaynak 2007; Burke et al. 2001). Few key examples of these, include: 1) land use regression modeling in support of children's health studies in El Paso, TX and in Detroit, MI (Smith et al. 2006; Mukerjee et al. 2006), 2) hybrid modeling for spatially and temporally resolved concentrations of PM, nitrogen oxides, carbon monoxide, benzene and other air toxics in New Haven, CT based on regional scale CMAQ modeling combined with local scale AERMOD modeling for point and roadway sources (Isakov and Özkaynak 2007), 3) alternative kriging and data fusion (i.e., combining atmospheric measurement and modeling results using hierarchical Bayesian methodologies for New York State), 4) modeling population exposures to PM in Philadelphia and in North Carolina (at census tract level) and for PM and soon for ozone, nitrogen dioxide and benzene in New Haven (at census block group level) using the ORD/NERL's SHEDS model (Burke et al. 2001, EPA 2004), and 5) modeling PM and ozone exposures in New York City, and PM exposures in Detroit by the SHEDS model (this work is being carried-out now).

Building on these capabilities demonstrated by NERL in the area of predicting personal exposures, a general strategy for examining the utility of refining the exposure metrics used in air pollution studies may involve the following 5 hierarchical tiers (Neas and Özkaynak 2006):

Tier 1

- A) Simple Spatial Surrogates (e.g. GIS data on source locations, proximity to sources, or number /strength of sources within a buffer zone)
- B) Ambient Monitoring data (e.g., central-site data)

Tier 2

- A) Air Quality Dispersion Models
- B) Land-Use Regression Models

Tier 3

- A) Intake Fraction Models
- B) Hierarchical Bayesian Models (i.e., combining modeling results with measurement data)

Tier 4

- A) Empirical Models (e.g., exposure predictions produced by using information on correlations between personal and ambient monitoring data, or exposure estimates based on time-activity weighted indoor and outdoor concentrations and using empirical estimates of indoor-outdoor concentration relationships)

Tier 5

- A) Mechanistic Models (such as the SHEDS, that incorporates cohort and household specific information on micro environmental factors (e.g., indoor sources, housing information, air exchange rate, removal/penetration and infiltration rates, etc.) and exposure factors (e.g., time-activity data, inhalation rates, etc.)

The goal of this work is to develop, apply and evaluate the relative merits of alternative personal exposure indicators or estimates of ambient PM and/or gases of health concern, in the context of air pollution health effects studies. It is expected that this research will involve the development and assessment of innovative approaches for exposure prediction used in air pollution health effects studies. However, given the limited scope and funding available for this solicitation, EPA/NERL does not expect collection and analysis of new data health or exposure data. Rather, EPA/NERL envisions a re-analyses of previously analyzed health data using more refined or advanced exposure metrics developed during the course of this new research. EPA/NERL anticipates a collaborative effort under this agreement with experts in the field of exposure assessment and environmental epidemiology to address the importance of developing and applying more refined or reliable exposure predictions in the investigation of ambient air pollution health effects. When addressing a research question/problem of common interest, collaborations between scientists and the institution's principal investigators are permitted under a cooperative agreement. These collaborations may include data and information exchange (such as supplying releasable model software or relevant model outputs for the appropriate study domain and/or time-period), providing technical input to experimental design and theoretical development, coordinating extramural research with in-house activities, the refinement of valuation endpoints, and joint authorship of journal articles on these activities. **Proposals should not identify EPA cooperators or interactions; specific interactions between EPA's investigators and those of the prospective recipient for cooperative agreements will be negotiated at the time of award.**

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Funding Priorities/Focus:

The purpose of this RFA is to solicit applications for a cooperative agreement to improve the exposure specification of future air pollution epidemiology studies. The proposed research will support EPA's strategic goals by reducing uncertainty in exposure assessments and risk assessments for individuals susceptible or at risk to adverse effects of air pollution.

This RFA solicits applications that must address *two or more* of the following key questions by carrying-out research that includes elements of *at least three* of the 5-tiered exposure refinement

strategy steps outlined above:

- How can atmospheric (e.g., CMAQ, AERMOD) and exposure models (e.g., SHEDS) be linked with other exposure-related data (e.g., air quality measurements, census data, housing information, time-activity data, transportation surveys, etc.) for improving the prediction of personal or population exposures in the analyses of the relationships between ambient air pollution and adverse health outcomes?
- How can the spatial and temporal resolution of ambient air concentration data used in support of epidemiologic studies be improved (e.g., by hybrid air quality modeling, hierarchical Bayesian modeling or fusion of measurement and modeling data, land-use regression modeling, etc.)?
- How can the characterization of exposures for an epidemiologic study be improved beyond relying only upon ambient concentration data (e.g., by accounting for infiltration factors, time-activity patterns, commuting patterns, etc.) using existing data sets?
- How can we evaluate alternative approaches for better characterizing inter- and/or intra-individual variability in personal exposures through appropriate air pollution epidemiology studies (e.g., longitudinal cohort, time-series, or cross-sectional inter- or intra-urban study designs)?

Proposals must include partnerships between exposure scientists and epidemiologists as an integral part of the project. Proposals should include an application of the methods or models developed for predicting exposures of study subjects/populations to either an ongoing or a reanalysis of a past epidemiologic study. Proposals should describe how the results of this research will be used to evaluate the utility of alternative exposure prediction methods in the investigation of health effects associated with air pollution. The overall goal is to enhance epidemiologic studies of ambient air pollution by incorporating more refined exposure estimates based on the results from currently available exposure models and measurements.

Environmental Results: This RFA seeks applications that will advance the following goals/objectives as identified in EPA's Strategic Plan (<http://www.epa.gov/ocfo/plan/2003sp.pdf>):

Goal: 1 - Clean Air and Global Climate Change
Objective: 1.6- Enhance Science and Research

Goal: 4 - Healthy Communities and Ecosystems
Objective: 4.4 - Enhance Science and Research

Several outputs will be developed from the research supported from this solicitation. Expected outputs, include reports, presentations, and articles in peer-reviewed journals that will incorporate measurements and models to improve the accuracy and reliability of the exposure prediction aspect of the epidemiologic studies linking morbidity and mortality health endpoints to ambient pollutants of health concern (i.e., PM, gases and air toxics). The outputs will contribute to important expected outcomes, including increasing the efficiency and effectiveness of federal and state/local air quality management strategies and reduced uncertainty in health risk assessments.

Note to applicant: The term “output” means an environmental activity or effort, and associated work projects, related to a specific environmental goal(s), (e.g., testing a new methodology), that will be produced or developed over a period of time under the agreement. The term “outcome” means the result, effect, or consequence that will occur from the above activity(ies) that is related to an environmental, behavioral, or health-related objective.

Statutory Authority for Award of Assistance: This research is authorized under the Clean Air Act, Section 103. The Clean Air Act authorizes the use of grants by EPA to promote research in the prevention and control of air pollution

Geospatial Information: It is anticipated that the agreement that is awarded will involve or relate to geospatial information which includes information that identifies the geographic location and characteristics of natural or constructed features or boundaries of the Earth or applications, tools, and hardware associated with the generation, maintenance, or distribution of such information. This information may be derived from, among other things, Geographic Positioning System (GPS), remote sensing, mapping, charting, and surveying technologies, or statistical data.

II. Award Information

Anticipated Amount of Individual Award: \$200,000

Anticipated Number of Awards: Two

Anticipated Funding: The EPA anticipates funding these awards over a period of 2 years, \$130,000 per award with the remainder anticipated to be provided before the end of FY 08, contingent upon availability of funds and satisfactory progress by the selected recipient(s).

Anticipated Project Period: 6/1/08 to 5/31/10

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. Discuss the specific approach for the study with the members of the project team.
2. Provide technical input to the details of the study design for the evaluation of alternative estimates of human exposures.
3. Coordinate extramural research with in-house research activities.
4. Provide technical input on a regular basis through scheduled meetings and monthly

conference calls.

5. Collaborate with the project team to identify milestones and discuss progress.
6. Provide code and documentation of available or releasable atmospheric dispersion and exposure models.
7. Provide outputs from EPA's in-kind application of air quality and/or exposure (SHEDS) model runs relevant to the project.
8. Participate in the application of alternative exposure metrics in the epidemiologic analysis of air pollution health effects.
9. Participate in the data analysis and interpretation of study results.
10. Participate in the preparation and review (to include co-authorship) of journal articles and 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. Profit-making firms are not eligible to receive awards. 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.

National laboratories funded by Federal Agencies (Federally-Funded Research and Development Centers, "FFRDCs") may not apply. FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation and regulations. They may participate in planning, conducting, and analyzing the research directed by the applicant, but may not direct projects on behalf of the applicant organization. The institution, organization, or governance receiving the award may provide funds through its assistance agreement from the EPA to an FFRDC for research personnel, supplies, equipment, and other expenses directly related to the research. However, salaries for permanent FFRDC employees may not be provided through this mechanism.

Federal Agencies may not apply. Federal employees are not eligible to serve in a principal leadership role on an assistance agreement, and may not receive salaries or augment their Agency's appropriations in other ways through awards made under this program.

The applicant institution may enter into an agreement with a Federal Agency to purchase or utilize

unique supplies or services unavailable in the private sector. Examples are purchase of satellite data, census data tapes, chemical reference standards, analyses, or use of instrumentation or other facilities not available elsewhere. A written justification for federal involvement must be included in the application. In addition, an appropriate form of assurance that documents the commitment, such as a letter of intent from the Federal Agency involved, should be included.

Cost Sharing Requirements: Institutional cost-sharing is not required. However, if the applicant intends to cost-share, a brief statement concerning cost-sharing should be added to the budget justification, and estimated dollar amounts must be included in the appropriate categories in the budget table.

Other Threshold Eligibility Criteria:

Administrative Eligibility Criteria: Applications must substantially comply with the application submission instructions and requirements set forth in Section IV of this announcement or else they will be rejected. In addition, where a page limit is expressed in Section IV with respect to the application and/or parts of the application, pages in excess of the page limitation will not be reviewed. Applications must be received by the EPA or through www.grants.gov on or before the solicitation closing date published in Section IV of this announcement. Applications received after the published closing date will be returned to the sender without further consideration. Also, applications exceeding the funding limits described herein will be returned without review.

Relevance Eligibility Criteria: Proposals that are found administratively acceptable will be subjected to a review for relevancy to EPA's mission to support advancement of environmental science. Proposals will be rejected if they are found to lack relevance. Examples of proposals that lack relevance 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; (e.g., it implies the primary purpose is to provide direct support to the Federal government).

Applications will be reviewed for threshold eligibility purposes prior to initiation of the technical and programmatic reviews under Section V. Proposals from ineligible applicants or proposals that do not meet the eligibility criteria set forth above will be returned without further review within 15 calendar days of the date of the ineligibility determination.

IV. Application and Submission Information

Applicants must submit a complete, detailed application to include all of the documents described in Section A below regardless of the mode of transmission. Additional guidance on completing the documents is available at EPA's Office of Grants and Debarment

<http://www.epa.gov/ogd/>). Applicants may submit either a hard-copy printed application or an electronic application through grants.gov (but not both) for this announcement. Applications may not be submitted via email. Instructions for both forms of submission follow.

A. Application Materials

The application is made through submission of the materials described below. *It is essential that the application contain all information requested and be submitted in the formats described.* The application must contain the following items:

1. Application For Federal Assistance (SF-424). Complete the form. There are no attachments. Please be sure to include the organization fax number and email address in Block 5 of the SF-424.

This form will be the *first page* of the application. Instructions for completion of the SF-424 are included with the form. (However, note that EPA requires that the entire requested dollar amount appear on the 424, not simply the proposed first year expenses.) The form must contain the original (or electronic) signature of an authorized representative of the applying institution. Please note that both the Principal Investigator and an administrative contact are to be identified in Section 5 of the SF-424. The applicant's DUNS number must be included. (See Section VIII for instructions on obtaining a DUNS number.)

2. Budget Information for Non-Construction Programs (SF-424A). Complete the form. There are no attachments. At a minimum, complete Section B- Budget Information and Section F- Other Budget Information. The total amount of federal funding requested for the project period should be shown on line 5(e) and on line 6(k) of SF-424A. If indirect costs are included, the amount of indirect costs should be entered on line 6(j). The indirect cost rate (i.e., a percentage), the base (e.g., personnel costs and fringe benefits), and the amount should also be indicated on line 22.

3. Key Contact List. EPA Key Contacts Form 5700-54 should include the Principal, Co-Investigators, and administrative contacts. A copy of this form should also be completed for major sub-agreements (contacts at the institutions of primary co-investigators).

4. Project Narrative and Supporting Documentation

The Project Narrative and Supporting documentation should be readable in pdf, MS Word or WordPerfect WP6/7/8 for Windows and consolidated into a single file.

Abstract (1 page)

The abstract is a very important document in the review process. Therefore, it is critical that the abstract accurately describes the research being proposed and conveys all the essential elements of the research. The abstract should include the information described below (a-h).

- a. Funding Opportunity Title and Number for this proposal

- b. **Project Title:** Use the exact title of your project as it appears in the application. The title must be brief yet represent the major thrust of the project. Because the title will be used by those not familiar with the project, strike a balance between highly technical words and phrases and more commonly understood terminology. Do not use general phrases such as "research on."
- c. **Investigators:** List the Principal Investigator, then the names and affiliations of each co-investigator who will significantly contribute to the project. Provide a web site URL or an email contact address for additional information.
- d. **Institution:** In the same order as the list of investigators, list the name, city and state of each participating university or other applicant institution. The institution applying for assistance must be clearly identified.
- e. **Project Period and Location:** Show the proposed project beginning and ending dates and the geographical location(s) where the work will be conducted.
- f. **Project Cost:** Show the total dollars requested from the EPA (include direct and indirect costs for all years).
- g. **Project Summary:** Provide three subsections addressing: (1) the objectives of the study (including any hypotheses that will be tested), (2) the experimental approach to be used (a description of the proposed project), and (3) the expected results of the project and how it addresses the research needs identified in the solicitation, including the estimated improvement in risk assessment or risk management that will result from successful completion of the proposed work.
- h. **Supplemental Keywords:** Without duplicating terms already used in the text of the abstract, list keywords to assist database searchers in finding your research. A list of suggested keywords may be found at: <http://www.epa.gov/ncer/rfa/forms>.

Research Plan and Quality Assurance Project Plan

Research Plan (15 pages)

Applications should focus on a limited number of research objectives that adequately and clearly demonstrate that they meet the RFA requirements. Explicitly state the main hypotheses that you will investigate, the data you will create or use, the analytical tools you will use to investigate these hypotheses or analyze these data, and the results you expect to achieve. Research methods must be clearly stated so that reviewers can evaluate the appropriateness of your approach and the tools you intend to use. A statement such as: "we will evaluate the data using the usual statistical methods" is not specific enough for peer reviewers.

This description must not exceed fifteen (15) consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins. This page limitation shall include all text, tables, figures, references, attachments, and appendices. While these guidelines establish the minimum type size requirements, applicants are advised that readability is of paramount importance and should take precedence in selection of an appropriate font for use in the proposal.

The description must provide the following information:

1. **Objectives:** List the objectives of the proposed research and the hypotheses being tested during the project, and briefly state why the intended research is important and

how it fulfills the requirements of the solicitation. This section should also include any background or introductory information that would help explain the objectives of the study. If this application is to expand upon research supported by an existing or former assistance agreement awarded with EPA, indicate the number of the agreement and provide a brief report of progress and results achieved under it (one to two pages recommended).

2. Approach/Activities: Outline the research design, methods, and techniques that you intend to use in meeting the objectives stated above (five to ten pages recommended).
3. Expected Results, Benefits, Outputs, and Outcomes: Describe the results you expect to achieve during the project (outputs), the potential benefits of the results (outcomes) and the plan for tracking and measuring the progress toward achieving the expected outputs and outcomes. This section should also discuss how the research results will lead to solutions to environmental problems and improve the public's ability to protect the environment and human health. A clear, concise description will help EPA and peer reviewers understand the merits of the research (one to two pages recommended).
4. General Project Information: Discuss other information relevant to the potential success of the project. This should include facilities, personnel expertise/experience, project schedules, proposed management, interactions with other institutions, etc. Applications for multi-investigator projects must identify project management and the functions of each investigator in each team and describe plans to communicate and share data (one to two pages recommended).
5. Appendices may be included but must remain within the 15-page limit.

Quality Assurance Project Plan (3 pages)

The USEPA operates a formal quality assurance (QA) program that applies to assistance agreements whenever environmental data are collected and/or used. Guidance for implementing EPA's QA program can be found at: <http://www.epa.gov/quality/>. For the purposes of this research, the applicant must provide a Quality Assurance Project Plan (QAPP) for secondary data that addresses the following items:

1. Title and Approval Page

Include signatures lines for the applicant, his/her quality system personnel, the NERL project officer, and his/her quality assurance manager.

2. Quality System Components

Describe the applicant's current organizational quality assurance program, including but not limited to:

- a. Who has responsibility for the quality control of projects?
- b. Where is this person in the organizational hierarchy?
- c. What quality control and assurance procedures are planned or in place for projects like the proposed, and are these procedures documented?

- d. How does the person responsible for quality assess and document the quality control exercised in projects and implement any necessary corrective actions, including those that require approval from the project's research lead?

3. Project Definition and Background

This information may be found in the Research Plan.

4. Data Quality Objectives (DQOs)

Include an explanation of data use and acceptance criteria (precision, accuracy, representativeness, completeness, and compatibility).

5. Project Organization and Responsibilities of the Researcher

Briefly describe how the project will be executed and who has responsibility for the various tasks. List licenses, certifications, and accreditations that are applicable to this project. Document how any items and services procured under this project will be determined to be of good quality and applicable to the needs of this project.

6. Data Sets, Documentation, and Reporting

Describe general considerations and QA requirements for the following issues:

- a. Source(s) of the existing (secondary) data/information and rationale for selecting the source(s) *(describe the planning process for data gathering operations and how the organization ensures that data or information collected for a project are of sufficient quality to satisfy the needs of the project);*
- b. Non-quality constraints on the existing (secondary) data/information (e.g., legal, programmatic, CBI) that affect its use in the project;
- c. How the data/information will be used in the project, e.g., augment or replace existing data/information, verify or validate existing data/information;
- d. Procedures for determining the quality of the existing (secondary) data/information, i.e., how and to what degree will the accuracy, precision, representativeness, completeness, and comparability of the data/information be determined for the purposes of the project; what are the limitations or uncertainties associated with the data/information;
- e. Reduction/validation procedures, including calculations and equations, for the existing (secondary) data/information that are specific to the project; *(for secondary data gathered from publication, provide a citation).*
- f. Plans for review of the project during operation (oversight). *(discuss how the applicant will test for quality problems with this project. Who is normally responsible for this process of testing? Who changes the methods within the project if change is indicated by these tests?).*

7. Reconciliation with Data Quality Objectives

Describe how issues which come up during the project and require adjustment to the DQOs

will be resolved.

Organizational Capabilities

A demonstration of the applicant's programmatic capability (separate from the Project Narrative) to successfully complete the proposed project. Applicants should at a minimum submit a list of projects of similar size, scope and relevance to the proposed project that the applicant's proposed PI and (if applicable) co-PIs have undertaken in the past five years with Federal and/or non-federal agencies. Include the title, the Principal Investigator, the total amount funded, the project period, a brief (1-3 lines) description of the project, and the record of resulting peer-reviewed publications. Provide a point of contact in the primary sponsor's organization with email address and telephone. The information provided will be used by the Agency in conjunction with other readily available information to evaluate the applicant's past performance. The Agency, as a part of the evaluation process, may contact the referenced sponsor to obtain more detailed information of the applicant's recent past performance in completing projects of similar size, scope and relevance.

Budget Narrative

Budget Narrative includes detailed, itemized budget estimates 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. If a subagreement is included in the application, provide a separate budget for the subagreement in the same format if the subagreement is greater than \$25k.

If amounts are budgeted for subcontracts, provide a description of the work that will be subcontracted and an explanation of why it must be subcontracted. Indicate whether the subcontracts will be awarded competitively or if not, what justification exists to make a non-competitive award. Any budget that includes amounts for subcontracts of 40% or more of the total direct costs will be subject to special review. Section IV.F, Partnerships, for a further discussion of proposed subcontracts.

Please note that institutional cost-sharing is not required. However, if you intend to cost-share, a brief statement concerning cost-sharing should be added to the budget justification, and estimated dollar amounts must be included in the appropriate categories in the budget table.

Describe the basis for calculating the personnel, fringe benefits, travel, equipment, supplies, contractual support, and other costs identified in the itemized budget and explain the basis for their calculation. (Special attention should be given to explaining the "travel," "equipment," and "other" categories.). For any proposed equipment, identify any tangible non-expendable personal property to be purchased which has an estimated cost of \$5,000 or more per unit and a useful life of more than one year. (Personal property items with a unit cost of less than \$5,000 are considered supplies.) Tips for preparing the budget support can be found at <http://www.epa.gov/ogd/recipient/tips.htm>.

Management Fees: When formulating budgets for proposals/applications, applicants must not include management fees or similar charges in excess of the direct costs and indirect costs at the rate approved by the applicants cognizant audit agency, or at the rate provided for by the terms of the agreement negotiated with EPA. The term "management fees or similar charges" refers to expenses

added to the direct costs in order to accumulate and reserve funds for ongoing business expenses, unforeseen liabilities, or for other similar costs that are not allowable under EPA assistance agreements. Management fees or similar charges may not be used to improve or expand the project funded under this agreement, except to the extent authorized as a direct cost of carrying out the scope of work.

Biographical Sketches

Biographical Sketches - 2-page curriculum vitae should be included for the Principal Investigator, co-principal investigator(s), and any other key personnel identified in the proposal.

B. Submission Instructions for Electronic Applications Using Grants.gov

The electronic submission of your application must be made by an official representative of your institution who is registered with Grants.gov and is authorized to sign applications for Federal assistance. For more information, go to <http://www.grants.gov> and click on “Get Registered” on the left side of the page. *Note that the registration process may take a week or longer to complete.* If your organization is not currently registered with Grants.gov, please encourage your office to designate an AOR and ask that individual to begin the registration process as soon as possible.

To begin the application process under this grant announcement, go to <http://www.grants.gov> and click on the “Apply for Grants” tab on the left side of the page. Then click on “Apply Step 1: Download a Grant Application Package and Instructions” to download the PureEdge viewer and obtain the application package for the announcement. To download the PureEdge viewer click on the “PureEdge Viewer” link. Once you have downloaded the viewer, you may retrieve the application package by entering the Funding Opportunity Number, EPA-ORD-07-28347, or the CFDA number that applies to the announcement (CFDA 66.511), in the appropriate field. You may also be able to access the application package by clicking on the button “Application” at the top right of the synopsis page for this announcement on <http://www.grants.gov> (to find the synopsis page, go to <http://www.grants.gov> and click on the “Find Grant Opportunities” button on the left side of the page and then go to Search Opportunities and use the Browse by Agency feature to find EPA opportunities).

Application Submission Deadline: Your organization’s AOR must submit your complete application electronically to EPA through Grants.gov (<http://www.grants.gov>) no later than 3:00 p.m. est on January 30, 2008.

Please submit *all* of the proposal/application materials described below.

The following forms and documents are required to be submitted under this announcement:

1. Application for Federal Assistance (SF-424)
2. Budget Information for Non-Construction Programs (SF-424A)
3. Key Contact List

4. Project Narrative and Supporting Documentation

Documents 1 through 4 listed under Application Materials in Section IV.A of this announcement should appear in the “mandatory Documents” box on the grants.gov Grant Application Package page.

For documents 1-3, click on the appropriate form and then click “Open Form” below the box. The fields that must be completed will be highlighted in yellow. Optional fields and completed fields will be displayed in white. If you enter an invalid response or incomplete information in a field, you will receive an error message. When you have finished filling out each form, click “Save”. When you return to the electronic Grant Application Package page, click on the form you just completed, and then click on the box that says, “Move Form to Submission List”. This action will move the document over to the box that says, “Mandatory Completed Documents for Submission.”

For document 4, you will need to attach electronic files. Prepare each of the documents as described above in Section IV.A.4 and save the documents to your computer as an MS Word, PDF or WordPerfect file. When you are ready to attach your proposal to the application package, click on “Project Narrative Attachment Form”, and open the form. Click “Add Mandatory Project Narrative File”, and then attach your proposal (previously saved to your computer) using the browse window that appears. You may then click “View Mandatory Project Narrative File” to view it. Enter a brief descriptive title of your project in the space beside “Mandatory Project Narrative File Filename”, the filename should be no more than 40 characters long. If there are other attachments that you would like to submit to accompany your proposal, you may click “Add Optional Project Narrative File” and proceed as before. When you have finished attaching the necessary documents, click “Close Form”. When you return to the “Grant Application Package” page, select “Project Narrative Attachment Form” and click “Move Form to Submission List”. The form should now appear in the box that says, “Mandatory Completed Documents for Submission”.

Once you have finished filling out all of the forms/attachments and they appear in one of the “Completed Documents for Submission” boxes, click the “Save” button that appears at the top of the Web page. It is suggested that you save the document a second time, using a different name, since this will make it easier to submit an amended package later if necessary. Please use the following format when saving your file: “Applicant Name – FY 08 (grant category; e.g., Assoc Prog Supp) – 1st Submission” or “Applicant Name – FY 08 (grant category) – Back-up Submission.” If it becomes necessary to submit an amended package at a later date, then the name of the 2nd submission should be changed to “Applicant Name – FY 08 (grant category) – 2nd Submission.”

Once your application package has been completed and saved, send it to your AOR for submission to the U.S. EPA through Grants.gov. Please advise your AOR to close all other software programs before attempting to submit the application package through Grants.gov.

In the “Application Filing Name” box, your AOR should enter your organization’s name (abbreviate where possible), the fiscal year (e.g., FY08), and the grant category (e.g., Assoc Prog Supp). The filing name should not exceed 40 characters. From the “Grant Application Package” page, your AOR may submit the application package by clicking the “Submit” button that appears at

the top of the page. The AOR will then be asked to verify the agency and funding opportunity number for which the application package is being submitted. If problems are encountered during the submission process, the AOR should reboot his/her computer before trying to submit the application package again. [It may be necessary to turn off the computer (not just restart it) before attempting to submit the package again.] If the AOR continues to experience submission problems, he/she should contact grants.gov for assistance (Phone: 1-800-518-4726, Email: <http://www.grants.gov/help/help.jsp>). If submission problems are not quickly resolved, contact the NERL electronic submission support person, Walt Stutts at 513/569-7487 or stutts.walter@epa.gov.

Application packages submitted through grants.gov will be time/date stamped electronically.

If you have not received a confirmation of receipt from EPA (not from grants.gov) within 30 days of the application deadline, please contact the individual identified in Section VII. Failure to do so may result in your application not being reviewed.

C. Submission Instructions for Printed Hard-Copy Applications

Submit a complete application including all of the documents identified in Section IV.A of this announcement. The complete application *must be* sent through regular mail, express mail, or a major courier to: **Claudette Mitchell, (D305-01), 4930 Page Rd., Durham, NC 27703 (for Courier/Federal Express) or Research Triangle Park, NC 27711 (for USPS).**

Because of security concerns, applications cannot be personally delivered. To be considered timely, printed applications must be received by 3:00 p.m. local time in RTP, NC on January 30, 2008 from the U.S. Postal Service or a major courier. Applications received after the deadline will not be considered and will be returned to the submitter. Printed hard-copy applications, including all documents stated in Section IV.A. above, must be submitted in the original with 3 copies and should be double-sided. Grant application forms can be found at <http://www.epa.gov/ogd/AppKit/application.htm>

D. Intergovernmental Review

Executive Order 12372, "Intergovernmental Review of Federal Programs," applies to most EPA programs and assistance agreements, unless the program or assistance agreement supports tribal, training/fellowships (other than Wastewater and Small Water Systems Operator training programs), and research and development (with some exceptions). The SF424 refers to this Executive Order Requirement. National research programs are generally exempt from review unless the proposals (a) require an Environmental Impact Statement (EIS), or (b) do not require an EIS but will be newly initiated at a particular site and require unusual measures to limit the possibility of adverse exposure or hazard to the general public, or (c) have a unique geographic focus and are directly relevant to the governmental responsibilities of a State or local government within that geographic area. To determine whether their state participates in this process, and how to comply, applicants should consult: <http://www.whitehouse.gov/omb/grants/spoc.html>.

E. Funding Restrictions

Funding of the awards is expected to be \$130,000 per award with the remainder funding anticipated to be provided before the end of FY08, contingent upon availability of funds and satisfactory performance.

F. Partnerships

EPA awards funds to one eligible applicant as the “recipient” even if other eligible applicants are named as “partners” or “co-applicants” or members of a “coalition” or “consortium”. The recipient is accountable to EPA for the proper expenditure of funds.

Funding may be used to provide subgrants or subawards of financial assistance to fund partnerships provided the recipient complies with applicable requirements for subawards or subgrants including those contained in 40 CFR Parts 30 or 31, as appropriate. Successful applicants must compete contracts for services and products and conduct cost and price analyses to the extent required by the procurement provisions of these regulations. The regulations also contain limitations on consultant compensation. Applicants are not required to identify contractors or consultants in their proposal. While applicants are not required to identify contractors or consultants in their proposal, if they do so the fact that an applicant selected for award has named a specific contractor or consultant in the proposal EPA selects does not relieve the applicant of its obligations to comply with competitive procurement requirements. Please note that applicants may not award sole source contracts to consulting, engineering or other firms assisting applicants with the proposal based solely on the firm’s role in preparing the proposal.

Successful applicants cannot use subgrants or subawards to avoid requirements in EPA grant regulations for competitive procurement by using these instruments to acquire commercial services or products from for-profit organizations to carry out its assistance agreement. The nature of the transaction between the recipient and the subawardee and subgrantee must be consistent with the standards for distinguishing between vendor transactions and subrecipient assistance under Subpart B Section .210 of OMB Circular A-133, and the definitions of “subaward” at 40 CFR 30.2(ff) or “subgrant” at 40 CFR 31.3, as applicable. EPA will not be a party to these transactions.

Section V of the announcement describes the evaluation criteria and evaluation process that will be used by EPA to make selections under this announcement. During this evaluation, except for those criteria that relate solely to the applicant's qualifications, past performance, and reporting history, the review panel will consider (to the extent applicable under any relevant criteria) the qualifications, expertise, and experience of

(i) an applicant's proposed subawardees/subgrantees identified in the proposal/application if the applicant demonstrates in the proposal/application that subaward/subgrant will be properly awarded consistent with the applicable regulations.

(ii) an applicant's proposed contractor if the applicant's proposal/application demonstrates that the contractor was selected in compliance with the competitive Procurement Standards in 40 CFR Part 30 or 40 CFR 31.36.

EPA will not consider the qualifications, experience, and expertise of proposed subawardees/subgrantees and/or contractors during the proposal/application evaluation process unless the applicant complies with these requirements.

G. Amendments

Amendments will be posted on grants.gov under this Funding Opportunity Number and the due date for applications will be extended if deemed appropriate.

H. Confidentiality

By submitting an application in response to this solicitation, the applicant grants the EPA permission to make limited disclosures of the application to technical reviewers both within and outside the Agency for the express purpose of assisting the Agency with evaluating the application. Information from a pending or unsuccessful application will be kept confidential to the fullest extent allowed under law; information from a successful application may be publicly disclosed to the extent permitted by law.

In accordance with 40 CFR 2.203, applicants may claim all or a portion of the application/proposal as confidential business information (for example, hypotheses or methodologies contained in the research narrative that the applicant wishes to protect from possible public disclosure). EPA will evaluate confidentiality claims in accordance with 40 CFR Part 2. Applicants must clearly mark applications/proposals or portions of applications/proposals they claim as confidential. If no claim of confidentiality is made, the EPA is not required to make an inquiry to the applicant otherwise required by 40 CFR 2.204(c)(2) prior to disclosure.

V. Application Review Information

Each application that meets the eligibility requirements set forth in Section III will be subjected to technical and programmatic reviews. The technical review will be conducted by a panel consisting of at least two non-EPA reviewers and one EPA reviewer who are able to demonstrate expertise and a lack of any conflict of interest. The purpose is to evaluate the scientific merit of the proposal and the capability of the applicant to complete the project as proposed. The programmatic review will be conducted by other qualified EPA personnel who are able to demonstrate a lack of any conflict of interest. The purpose is to evaluate the applicant's past performance in conducting projects of similar size, scope and relevance. The following criteria will be used in the evaluation process:

Technical Evaluation Criteria

1. Adequacy of the Technical Approach (60%)

- (1) Background, need, and hypotheses: The applicant demonstrates a clear understanding of the scientific issues and goals of the research. The proposed hypotheses are sound

and address the issues and can be anticipated to lead to a substantial improvement in the prediction human exposures as part of investigation of the associations between air pollution and health (10%)

- (2) The applicant's general technical, statistical, and methodological approaches for conducting the proposed study are appropriate and adequate to test the proposed hypotheses, are scientifically sound, and have a high likelihood of success (10%)
- (3) The proposed approach describes and demonstrates how various tiered methodologies can be used for improving exposure predictions in testing the associations between ambient air pollution and observed health impacts (15%)
- (4) The proposal demonstrates innovative approaches in evaluating the value-added by using more precise and state-of-the art exposure metrics to the outcome of air pollution epidemiology studies (10%)
- (5) The applicant has identified a suitable and a promising existing epidemiologic data for a study location and a period with adequate air quality data, in order to be able to perform the proposed research that will adequately test the hypotheses (5%)
- (6) The applicant clearly demonstrates the capabilities and experience conducting the proposed exposure and epidemiologic analysis (5%)
- (7) The applicant presents a plan that will adequately track and measure progress toward achieving the anticipated environmental outputs and associated outcomes of the proposed research (5%)

2. Qualifications of the proposed key personnel and adequacy of time commitment (15%)

3. Institutional capability including laboratory space and equipment that will be available to complete the project (10%)

4. Quality Assurance Project Plan that describes the organization's approach to using data of known and adequate quality (5%)

5. Programmatic Evaluation Criterion (10%)

The applicant's demonstration of the programmatic capability to successfully carry out the proposed project taking into account such factors as its: (i) past performance of the proposed Lead Principal Investigator and (if applicable) co-Principal Investigator in successfully completing federally or non-federally funded assistance agreements of similar size, scope and relevance to the proposed project during the past five years, (ii) history of meeting reporting requirements on prior or current assistance agreements (during the past five years) with federal and/or non-federal governmental organizations and submitting acceptable final technical reports, and (iii) past performance in documenting and/or reporting on its progress towards achieving the expected outcomes and outputs (e.g., results) under prior or current assistance agreements (during the past five years) with federal and/or non-federal governmental organizations (and if such progress was not made whether the documentation and/or reports satisfactorily explained why not).

Organizations that have no relevant or available past performance and/or reporting information will be given a neutral rating for those criteria. In evaluating applicants under this criterion the Agency

may consider information from other sources including agency files (e.g., the EPA's Grantee Compliance Assistance Initiative Database) and prior/current grantors (e.g., to verify and/or supplement the information provided by the applicant).

Other Factors: When two or more of the highly rated proposals receive equivalent rankings, the respective budgets will be evaluated by EPA staff for cost reasonableness and cost realism in order to determine which applicant will receive the award. The proposal that is determined to be the most reasonable/realistic will be selected for award. The amount of cost sharing proposed (if any) will not result in additional points for any applicant, but will be considered in the evaluation of the reasonableness and realism of the overall budget.

Review and Selection Process:

Evaluation Review Process: The eligibility review discussed in Section III will be conducted by EPA personnel who are not part of the technical review panel. The technical review panel, which reviews the technical proposal for scientific merit and organizational capabilities, shall consist of at least one internal EPA reviewer and at least two non-EPA reviewers who are able to demonstrate technical expertise and a lack of any conflict of interest. The technical review panel will review the proposal against the criteria above identified as Technical Evaluation Criteria and rank the proposal based upon this evaluation. The programmatic review will be conducted by one or more EPA reviewers who are not part of the technical evaluation panel and who are able to demonstrate a lack of any conflict of interest. The programmatic reviewer(s) will review the proposal against the criteria identified as Programmatic Evaluation Criteria above and rank the proposals based upon this evaluation. The results of the Technical and Programmatic Evaluations will be combined to determine the overall ranking of each evaluated applicant.

Source Selection: EPA will make a selection of the applicant(s) for award based upon the combined rankings of the technical and programmatic reviews and the other factors discussed above. EPA may negotiate changes to the proposal with the selected applicant(s) so long as they do not affect the integrity of the competition. 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. The Decision Official is an Office of Research and Development (ORD) manager who will determine which applicant(s) should receive the award.

Rejection Factors: Applications may be rejected because they fail to comply with the administrative requirements of the RFA, they are found to lack relevancy, they are judged technically and/or programmatically 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 awards.

Anticipated Announcement and Award Dates: The anticipated award date is 06/01/2008

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.

Disputes: Assistance agreement competition-related disputes will be resolved in accordance with the dispute resolution procedures published in 70 FR (Federal Register) 3629, 3630 (January 26, 2005) which can be found at <http://www.epa.gov/ogd/competition/resolution.htm>. Copies of these procedures may also be requested by contacting the Agency Contact identified in Section VII.

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 quality assurance document, i.e., Quality Assurance Project Plan (QAPP), acceptable to EPA shall be due within 45 calendar days of completion of the final study design.
- Prior approval of the protocol for protection of human subjects by an Institutional Review Board, in the event the research involves use of existing individual-level data which could make it possible for them to be linked back to individuals.
- 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.
- The nature and extent of collaboration between EPA and the recipient.

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 RFA is Claudette Mitchell at:

US Environmental Protection Agency
(D305-01)

(Courier/Federal Express)
4930 Page Rd.
Durham, NC 27703

(USPS)
Research Triangle Park, NC 27711

Telephone: 919-541-3183

E-mail: Mitchell.claudette@epa.gov (applications may not be submitted via email)

If unable to reach Claudette Mitchell, contact Mr. Walter Stutts at:

Telephone: (513) 569-7487

E-mail: stutts.walter@epa.gov

VIII. Other Information

Questions: Questions should be submitted in writing by January 16, 2008. Do not attempt to seek information regarding this RFA from any source other than those identified in Section VII as the information provided may be erroneous. Questions that are considered significant will be answered via an amendment to this RFA.

Animal and Human Subject Research:

a. Human Subjects: A grant applicant must agree to meet all EPA requirements for studies using human subjects prior to implementing any work with these subjects. These requirements are given in 40 C.F.R. § 26. For observational studies involving children, pregnant women, or nursing mothers please refer to Subparts B & D of 40 C.F.R. § 26. U.S. Department of Health and Human Services regulations at 45 C.F.R. § 46.101 (e) have long required "...compliance with pertinent Federal laws or regulations which provide additional protection for human subjects." EPA's regulation at 40 C.F.R. Part 26 is such a pertinent Federal regulation. Therefore, the applicant's Institutional Review Board (IRB) approval must state that the applicant's study meets the EPA's regulations at 40 C.F.R. § 26. No work involving human subjects, including recruiting, may be initiated before the EPA has received a copy of the applicant's IRB approval of the project and the EPA has also provided approval. Where

human subjects are involved in the research, the recipient must provide evidence of subsequent IRB reviews, including amendments or minor changes of protocol, as part of annual reports.

b. Animal Welfare: A grant recipient must agree to comply with the Animal Welfare Act of 1966 (P.L. 89-544), as amended, 7 U.S.C. 2131-2156. The recipient must also agree to abide by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training." (50 Federal Register 20864-20865 (May 20,1985))

* This clause applies if a research facility (defined as any school (except elementary or secondary), institution, organization or person) receives funds under a grant from a federal agency for the purpose of carrying out research, tests, or experiments involving animals.

c. Data Access and Information Release: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. If such data are requested by the public, the EPA must ask for it, and the grantee must submit it, in accordance with A-110 and EPA regulations at 40 C.F.R. 30.36.

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.