Guidance for Preparing Assistance Application for

Human Health Effects of Environmental Pollutants

NATIONAL HEALTH AND ENVIRONMENTAL EFFECTS RESEARCH LABORATORY
HUMAN STUDIES DIVISION

Overview Information

Federal Agency Name: U.S. Environmental Protection Agency (EPA), Office of Research and Development (ORD)
Funding Opportunity Title: Human Health Effects of Environmental Pollutants
Catalog of Federal Domestic Assistance Number: 66.511 Office of Research and Development Consolidated Research
Date: The application deadline is June 30, 2014.

Overview:

This document provides guidance and establishes minimum requirements for the University of North Carolina at Chapel Hill (UNC-CH) to submit a noncompetitive application for EPA funds. The anticipated total award for an estimated 7-plus year period of performance will not exceed $ 9,800,000. The purpose of the cooperative agreement is to conduct research on the effects of environmental pollutants on humans. It is anticipated that the agreement will be performed by the UNC-CH Center for Environmental Medicine, Asthma and Lung Biology (CEMALB or Center). The awarding instrument will be a cooperative agreement. There is no cost share or matching requirement for these funds.

I. Funding Opportunity Description

A. Introduction

The U. S. Environmental Protection Agency announces extramural funding for a cooperative agreement to address priority clinical research areas. It is anticipated that the awardee will engage in cooperative studies with investigators of the Environmental Public Health Division (NHEERL/ORD), located on the Medical School Campus of the University of North Carolina, Chapel Hill. Although it is expected that the majority of studies done under this cooperative agreement will address issues related to air pollution, opportunities may also arise in which it would be appropriate to conduct cooperative studies which address other environmental issues that can impact human health relevant to EPA's mission, such as water quality or contaminants exposure and health effects related to man-made chemicals, or providing information and tools that could result in healthier communities . This document provides relevant background information, summarizes EPA's interest in supporting this cooperative agreement, and describes eligibility requirements and application instructions for the program.

B. Statutory Authority

EPA expects to award this assistance agreement under the following grant authorities: Clean Air Act, as amended, Section 103; the Safe Drinking Water Act, as amended, Section 1442; and the National Environmental Policy Act, as amended, Section 102.

C. Alignment with EPA's Research Action Plans

The proposal must support one or more components of ORD's four Research Action Plans:

Air, Climate and Energy (ACE): The ACE program provides the critical science to develop and implement the National Ambient Air Quality Standards under the Clean Air Act. The research program fosters innovative approaches to ensure clean air in the context of a changing climate and energy options.
Safe and Sustainable Water Resources (SSWR): The SSWR program undertakes the development of sustainable solutions to 21st century water resource problems by integrating research on social, environmental and economic outcomes to provide long-lasting solutions.
Chemical Safety for Sustainability (CSS): The CSS program leads the development of innovative science to support safe, sustainable design and use of chemicals and materials required to promote human and environmental health, as well as to protect vulnerable species and populations.
Sustainable and Healthy Communities (SHC): The SHC program provides useful science and tools for decision makers at all levels to help communities advance sustainability as well as achieve regulatory compliance.

It is anticipated that most of the research done under the auspices of this cooperative agreement will be targeted to ACE, which is the focal point of research done by EPA investigators in Chapel Hill. However, some work may also be targeted to other Research Action plans.

D. Measuring Environmental Results

Measuring Environmental Results: Outputs and Outcomes

Pursuant to EPA order 5700.7, Environmental Results under EPA Assistance Agreements, EPA requires that all grant recipients adequately address environmental outputs and outcomes. Outputs and outcomes differ both in their nature, and in how they are measured.

Outputs: The term *output* means an environmental activity, effort, and/or associated work products related to an environmental goal and objective, that will be produced or provided over a period of time or by a specified date. Outputs may be quantitative or qualitative but must be measurable during an assistance agreement funding period.

Expected outputs from the projects funded under this assistance may include but are not limited to the following:

- Publications in peer-reviewed scientific journals;
- Presentations at national and international scientific meetings; and
- Undergraduate, graduate, and postdoctoral students trained in conducting research on the effects of pollutants on human health.

Outcomes: The term *outcome* means the result, effect, or consequence that will occur from carrying out an environmental program or activity that is related to an environmental programmatic goal objective. Outcomes may be environmental, behavioral, health-related or programmatic in nature, but must be quantitative. They may not necessarily be achievable within an assistance agreement funding period. Examples of expected generalized outcomes from the projects funded under this assistance may include but are not limited to the following:

- A better understanding of the health effects of air pollutants on humans;
- A better understanding of the health effects of contaminated drinking water on humans;
- A better understanding of genomics, computational methods, and bioinformatics to improve risk assessments of the health effects of environmental pollutants on humans; and

- A better understanding of biological processes and mechanisms of action in humans in response to exposure to environmental pollutants.

II. Award Information

A. Amount of Funding Available

EPA anticipates one award, for a total agreement value not to exceed $9,800,000.

B. Funding Type

The agreement will be incrementally funded based on satisfactory progress, availability of funds, and identification of mutually agreeable projects. This award will be funded through a cooperative agreement with substantial involvement by EPA. Substantial involvement may include:

- Approval of key personnel qualifications;
- Providing access to unique EPA facilities and equipment;
- Consultation on, review of, and concurrence on new projects;
- Approval of specific phases of large projects before the recipient proceeds to the next phase;
- Assisting with some of the project activities;
- Coauthoring manuscripts;
- Reviewing and commenting on progress reports.

This award is being made in the form of a cooperative agreement and therefore requires substantial involvement and interaction between the applicant and the EPA. Accordingly, at least 50% of the direct base funding (not to include in-kind contributions) received by the recipient under this agreement will be used to support their participation in joint research projects with the EPA. Such projects will have substantial involvement by both EPA and the applicant in their design, implementation or conduct of the research.

C. Start Date/Program Duration

EPA anticipates that the start date of this project would be no later than January 1, 2015. We anticipate the period of performance would not exceed December 31, 2021.

D. Miscellaneous

Funding for this agreement is not guaranteed and is subject to the availability of funds as well as other factors identified in this announcement. EPA reserves the right to partially fund proposals/applications by funding discrete activities, portions, or phases of proposed projects.

III. Eligibility Information

A. Who May Apply?

Any award resulting from this application will be made noncompetitively to the University of North Carolina at Chapel Hill based on EPA Order 5700.5A1, the Assistance Agreement Competition Policy, Section 12.a.(6) (Public Interest) as a result of the close proximity of unique and specialized equipment and facilities of both the recipient and the EPA that are necessary for the successful performance of the program.

B. Funding Restrictions and Requirements/Cost Sharing or Matching Requirements
There is no statutory or regulatory match requirement for this program. EPA grant or cooperative agreement funds may only be used for the purposes set forth in the assistance agreement, and must be consistent with the statutory authority for the award. Grant or cooperative agreement funds may not be used for matching funds for other Federal grants, lobbying, or intervention in Federal regulatory or adjudicatory proceedings, and may not be used to sue the Federal government or any other government entity.

IV. Application and Submission Information

Program Narrative

The proposal should be responsive to some or all of the following research areas. Proposed research not linked with these areas will require a separate justification.

Multipollutant Interactions
NAAQS pollutants are currently regulated individually, but people don't inhale a single pollutant at a time. To adequately protect public health, research is needed to understand whether components of a pollutant mixture interact in such a way that the toxicity of the mixture is greater than the sum of the toxicity of the individual components of the mixture (i.e. synergism). Research is also needed to understand whether exposure to one pollutant sensitizes an individual so that exposure to a second pollutant hours later results in an enhanced response. This question could be addressed by epidemiology panel studies, controlled human or animal exposure studies, or in vitro studies, and could include interactions between NAAQS pollutants, NAAQS pollutants and air toxics, or NAAQS pollutants and individual components or particulate air pollution (e.g. LPS). Such studies should focus on pollutant mixtures and interactions to which people are likely to be exposed.

Health Effects Associated with Inhaled Particulate Pollutants Derived from Specific Sources
Current EPA standards are mass based and assume that pollutants derived from all sources are equally toxic. But recent research indicates that some sources (e.g. traffic) emit more potent pollutants than others. This issue could be addressed by studies which examine and compare the health effects of pollutants derived from specific sources (e.g. diesel exhaust, wood smoke, bioaerosols). Panel studies in which individuals are brought into close proximity to a specific source (e.g. near a busy road), controlled human or animal exposure studies to specific sources, as well as relevant in vitro screening of multiple sources for comparative potency could all be conducted.

Susceptibility to Air Pollutants
Many air pollutants target subgroups of individuals, who are more responsive, or more likely to suffer from exacerbation of their disease. Increasing our understanding of who is susceptible to the effects of air pollutants and why they are susceptible will improve the scientific basis for air quality standards. Susceptibility could be defined by age, gender, race, disease status, genetic/epigenetic profiles, or lifestyle choices (e.g. smoking, obesity). To address the questions

of susceptibility, studies may employ any number of approaches including *in vitro*, animal, controlled human exposure, or panel studies. Studies are especially encouraged that seek to characterize the role of genetic or epigenetic factors in contributing to susceptibility to air pollutants. Studies which describe the mechanisms underlying susceptibility are preferable to studies which merely identify a susceptible population.

Social Determinants of Health

There is an increasing realization that the social environment can interact with the physical environment to worsen or mitigate health effects. Research is needed to understand this link. The social environment can be defined as the social setting in which people live. Understanding how this affects an individual's biology and, in turn, how this results in different responses to environmental pollutants should be addressed. This may include studies of the role of psychological stress or socioeconomic and cultural factors in determining biological responses. This issue could be addressed through animal, clinical or epidemiologic studies.

Intervention Studies

Millions of Americans live in areas that are not currently in attainment with NAAQS standards. Research is needed to identify simple over the counter agents that could protect people from the harmful effects of air pollutants, especially susceptible populations. Such studies might include the use of agents to protect against the pulmonary effects of oxidant pollutants such as ozone (e.g. anti-oxidants) or agents that might protect against the cardiovascular effects of particulate air pollution (e.g. fish oil enriched in omega-3 fatty acids). Studies that seek to understand why an agent might be protective are preferable to studies which merely identify such agents.

Biological Mechanisms

Epidemiology studies report associations between exposure to air pollutants and increased mortality or morbidity. However, the mechanisms by which air pollutants cause adverse health effects are not yet adequately understood. Research is needed to understand these mechanisms, which may provide biological plausibility to the epidemiology studies. For the purposes of this cooperative agreement, mechanistic research refers to hypothesis-driven studies that seek to define the molecular, biochemical, cellular, or physiological mechanisms which underlie a biological change induced by exposure to a pollutant. The use of state-of-the-art molecular biology, genetic and genomic, proteomic, and metabolic profiling techniques to address these questions is encouraged.

Specific Requirements

Since this is a cooperative agreement, it is anticipated that most, if not all, projects will be defined jointly between EPHD investigators and the awardee. Furthermore, because of the length of this cooperative agreement, it is not feasible to define a concrete set of research studies that will span the entire length of the agreement. Rather, the applicant should define a set of broad research objectives related to the question described above, and then present more detailed studies which would occur during the first three years of the cooperative agreement. These

projects should be illustrative in nature rather than an attempt to describe every potential study that may be initiated. A final description of projects will benefit from discussions between the awardee and the EPHD. In addition, the applicant should provide a table with a description of all projects they propose doing in the first two years of the proposal, and the potential EPA collaborators for each of the projects. The applicant should also provide a table of current and proposed grants they have received from sources other than the EPA. Given the length of this agreement, it is also possible that after three years, both the EPA and the awardee may decide to add new areas of research or de-emphasize current ones, to ensure the research is addressing important and relevant scientific issues.

The awardee should describe any units that may be needed to accomplish the research objectives, including an Administrative unit and their role in providing overall oversight, coordination, and integration of agreement research activities, QA and safety issues, and other pertinent issues.

Specific instructions are as follows:

1. **The Application Must Contain a Table of Contents**

   Provide a list of the major subdivisions of the application indicating the page number on which each section begins.

2. **The Application Must Contain Abstracts** (1 page abstract for the Center as a whole; 1 page abstract for each proposed research project identified in #4 below)

   The abstract should include the information described below. Examples of abstracts for current grants may be found on the NCER web site.

   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, use more commonly understood terminology. Do not use general phrases such as "research on."

   Investigators: List the Lead PI, then the name(s) of each co-PI who will significantly contribute to the project.

   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 (outputs/outcomes) 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.

3. **The Application Must Contain a Center Description (3 pages)**

The CEMALB should describe the overall goals, objectives, and approach for the Center, including how the Center will pursue an integrated, multi-disciplinary and thematic approach to the problems to be investigated. The Center's research projects should complement each other and reflect the Center's overall approach. The Center description must describe the expertise and qualifications of participating investigators and discuss the complementary support provided by each partner and collaborating organization.

4. The Application Must Contain Research Project Plan Descriptions (4 pages per research project description)

The CEMALB may include up to five projects that address the research topics described in above. Explicitly state the main hypotheses that will be investigated, the data that will be created or used, the analytical tools used to investigate these hypotheses or analyze these data, and the results that are expected to be achieved. It is not necessary, nor is space provided to go into great detail on research methodology for each project.

Each 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.
2. Approach/Activities: Outline the research design, methods, and techniques that you intend to use in meeting the objectives stated above.
3. Expected Results, Benefits, Outputs, and Outcomes: Describe the results you expect to achieve during the project (outputs) and the potential benefits of the results (outcomes).
4. General Project Information: Discuss other information relevant to the potential success of the project. This might include facilities, personnel expertise/experience, interactions with non-Center researchers, etc.

5. The Application Must Contain a Quality Management Plan (4 pages)

For projects involving data collection or processing, environmental measurements, or modeling, EPA requires a Quality Management Plan (QMP) describing the Center's policies and procedures that assure research results satisfy the intended objectives. The QMP provided with the application must contain, at a minimum, the information below.

Summary - A discussion of the overall quality assurance and quality control needs of the Center and the objectives of their Quality Assurance and Quality Control (QA/QC) policy.

1. Organization and Management - This section should include a chart that identifies:

- all of the components (research project or unit activity) of the Center;
- the Principal Investigator or overall manager for each component;
- the QA Manager who oversees the quality system for the Center, and how the QA manager reports to the Center Director or lead PI;
- the person(s) responsible for QA/QC activities for each component and how they report to the QA Manager.
- the specific responsibilities of the QA Manager and any other personnel with QA responsibilities;
- how the Center will maintain effective communications throughout the management structure.

2. **Quality System** - This section should include brief discussions of:

    - how the Center's research activities will be reviewed and evaluated to ensure quality;
    - how staff will be trained, and who will be responsible for training and oversight of QA practices during conduct of the research;
    - how data will be stored and made available to Center personnel and to the public; and
    - how the Center's QA/QC procedures will be reviewed and evaluated, including how recommended changes will be implemented.
    - how the quality of previously collected data will be determined appropriate for its stated use;
    - how data will be managed (collected, backed-up, collated, transferred, and stored) to ensure that the quality is maintained and documented;
    - how sample sizes will be selected and demonstrated to be sufficient to test hypotheses or meet specific objectives;

3. **Documentation and Records** - Describe or reference the procedures the Center will use for identifying and maintaining QA and QC related documents and records.

6. EPA Human Subjects Research (HSR)

All human research studies conducted or supported by EPA are governed by EPA regulations at 40 CFR Part 26 (Protection of Human Subjects). This includes the Basic Federal Policy for the Protection of Human Research Subjects, also known as the Common Rule, at subpart A and additional prohibitions and special protections for pregnant women, nursing women, and children in research conducted or supported by EPA at subparts B, C, and D. Depending upon the type of research being conducted, additional subparts of 40 CFR Part 26 may be relevant.

Procedures for the review and oversight of human research subject to 40 CFR Part 26 are also provided in EPA Order 1000.17 Change A1 (PDF) (41 pp, 333 K). These include review of projects for EPA-supported human research by the EPA Human Subjects Research Review Official (HSRRO). EPA Order 1000.17 Change A1 requires preliminary approval by the HSRRO of all proposed EPA-supported human research before the agreement can be entered into. Additional requirements must be met and final approval received from the HSRRO before the research can begin. When reviewing human observational exposure studies, EPA Order 1000.17 Change A1 requires the HSRRO to apply the principles described in the Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES) (EPA/600/R-08/062) (PDF) (133 pp, 1.21 MB) document and grant approval only to studies that adhere to those principles.

NOTE: All human research proposed as part of this Agreement must follow policies set forth in the most recent NHEERL Human Research Guidance Document, a copy of which will be provided upon award of the Cooperative Agreement.

7. **Administrative Unit** (3 pages)

The Center shall have an Administrative Unit which provides oversight, coordination and integration of the Center's activities, and which interfaces with EPA management and key investigators. Describe how the Administrative Unit will coordinate the research activities and how the program will be integrated internally. Indicate how programmatic and funding decisions will be made; how investigators from different disciplines within the Center will communicate on a regular basis about the development and progress of Center projects; how project objectives will be successfully achieved in a timely manner in accordance with project schedules and milestones; how progress toward achieving the expected results (outputs and outcomes) will be tracked and measured; who will set priorities and who will ensure the quality of the research. The approach, procedures and controls for ensuring that awarded grant funds will be expended in a timely and efficient manner should also be described.

The administrative unit description should also address how the Center will disseminate research findings and other information. The description should explain how products, research results, and findings will be internally reviewed and then disseminated to appropriate stakeholders.

The Center must be led by an overall Director who will provide oversight, coordination, and integration of the Center's activities. The Director assumes responsibility to maintain contact with and update the EPA Project Officer (PO) regarding progress of research and also provides the PO with timely reporting of operational and or budget issues that may arise. Describe the duties of administrative staff and their qualifications and contributions to the specialized needs and conduct of the Center's research activities.

8. **Research Support Unit(s) (2 pages per unit)**

If appropriate and desired, a Center may elect to have up to two Research Support Units (cores) that provide a technique, service, or instrumentation that will enhance research efforts across specific projects. Examples of such facilities are analytical chemistry laboratories, statistics centers, etc. The application must provide a compelling rationale

for why such a unit is needed and how it will be used by multiple projects within the proposed center.

9. References

References cited are in addition to other page limits (e.g. research plan, quality management plan).

10. Budget and Budget Justification

a. Budget

Prepare a master budget table using "SF-424A Budget Information for Non-Construction Programs" (aka SF-424A), available in the Grants.gov electronic application package and also at Forms and Standard Instructions Download Page. Only complete "Section B-Budget Categories". Provide the object class budget category (a.-k.) amounts for budget years 1-4 under the Grant Program, Function or Activity heading. Each column reflects a separate budget year. For example, Column (1) reflects budget year 1. Provide a separate 424A with the total budget for years 1-4 in Column (1) and the remaining years in the following columns. Column 5 of the second 424A will display the overall project total.

Also provide separate SF-424As for each individual research project proposed as well as for the administrative unit and each facility support unit. Additional SF-424As may be downloaded at Forms and Standard Instructions Download Page. Attach the additional SF-424As to the Project Narrative.

b. Budget Justification *[2 pages)*

Describe the basis for calculating the personnel, fringe benefits, travel, equipment, supplies, contractual support, and other costs identified in the SF-424A.

Budget information should be supported at the level of detail described below:

1. Personnel: List all staff positions by title. Give annual salary, percentage of time assigned to the project, total cost for the budget period, and project role. Compensation paid for employees engaged in grant activities must be consistent with payments for similar work within the applicant organization. Note that for salaries to be allowable as a direct charge to the award, a justification of how that role will be directly involved in a project must be provided.
2. Below is a sample computation for Personnel:

Position/Title	Annual Salary	% of Time Assigned to Project	Cost
Project Manager	$70,000	50%	$ 35,000
Env. Specialist	$60,000	100%	$ 60,000
Env. Health Tech	$45,000	100%	$ 45,000

Total Personnel	**$140,000**

3. Fringe Benefits: Identify the percentage used. Fringe benefits are for the personnel listed in budget category (1) above and only for the percentage of time devoted to the project.
4. Travel: Estimate the number of trips, purpose of each trip, and estimated costs for each trip. Note that international travel that uses EPA funds must have prior EPA approval.
5. Equipment: Identify all tangible, non-expendable personal property to be purchased that has an estimated cost of $5,000 or more per unit and a useful life of more than one year. Details such as the type of equipment, cost, and a brief narrative on the intended use of the equipment for project objectives are required. Each item of equipment must be identified with the corresponding cost. General-purpose equipment (office equipment, etc.) must be justified as to how it will be used on the project. (Property items with a unit cost of less than $5,000 are considered supplies.)
6. Supplies: "Supplies" means tangible property other than "equipment." Identify supplies to be used under the project. This may include: software, office supplies, and laboratory supplies such as reagents, chemicals and glassware. Specifically identify computers to be purchased or upgraded.
7. Contractual: Specify the amount you anticipate expending for services/analyses or consultants and specify the purpose of the contracts and estimated cost. **Any procurement of services from individual consultants or commercial firms (including space for workshops) must comply with the competitive procurement requirements of 40 CFR Part 30.40-30.48 or 40 CFR 31.36, as appropriate. Sub-awards may not be used to acquire services from consultants or commercial firms. Please see Contracts and Sub-awards for more details.**
8. Other: List each item in sufficient detail for the EPA to determine the reasonableness of its cost relative to the research to be undertaken. "Other" items may include publication costs, long distance telephone charges, and photocopying costs.
9. Indirect Costs: Indirect costs are those incurred by the applicant for a common or joint purpose that benefit more than one cost objective or project, and are not readily assignable to specific cost objectives or projects as a direct cost. In order for indirect costs to be allowable, the applicant must have a negotiated indirect cost rate (e.g., fixed, predetermined, final or provisional), or must have submitted a proposal to their cognizant agency. If indirect costs are included in the budget, identify the cognizant agency and the approved indirect rate. If your organization does not have a cognizant agency, please note that in the budget justification and provide a brief explanation for how you calculated your indirect cost rate.

11. Resumes

Provide resumes for each investigator and important co-worker. Do not include resumes of consultants or other contractors. The resume for each individual must not exceed two consecutively numbered (bottom center), 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

12. Current and Pending Support

Complete a current and pending support for each PI. Do not include current and pending support for consultants or other contractors. Include all current and pending research regardless of source.

13. 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.

14. Application Review Information

Peer Review

The application will be reviewed by appropriate external technical peer reviewers. This review is designed to evaluate the application according to its scientific merit. The individual external peer reviewers include non-EPA scientists, engineers, social scientists, and/or economists who are accomplished in their respective disciplines and proficient in the technical subjects they are reviewing. Reviewers will receive electronic copies of all applications, as well as instructions for preparing a written review.

The CEMALB will be required to address in writing any comments or deficiencies identified by the peer reviewers. The CEMALB response will be transmitted to the EPA project Officer.

Programmatic Review

The application will undergo an internal programmatic review, conducted by appropriate EPA personnel. The purpose of the programmatic review is to ensure an integrated research portfolio for the Agency; The EPA will consider information provided by the applicant and may consider information from other sources.

15. Reporting:

The cooperative agreement recipient must agree to provide annual progress reports and a final report with an executive summary to the EPA Project Officer. Findings are expected to be published in peer reviewed journals in a timely manner and follow EPA guidelines for clearance prior to publication. In addition, the awardee will have to produce a quarterly listing of all its on-going, completed and pending projects for the

then current fiscal year. The listing should include the following information: project title, IRP No., PI, UNC collaborators, EPA collaborators, the responsible organization, the project's program (as found in section IV), its status and any pertinent comments.

Acknowledgement of EPA Support: EPA's full or partial support must be acknowledged in journal articles, oral or poster presentations, news releases, interviews with reporters and other communications. Any documents developed under this agreement that are intended for distribution to the public or inclusion in a scientific, technical, or other journal shall include the following statement:

"This publication (article) was developed under Assistance Agreement No. _____, awarded by the U.S. Environmental Protection Agency to the Center for Environmental Medicine, Asthma and Lung Biology at the University of North Carolina at Chapel Hill. It has not been formally reviewed by the EPA. The views expressed in this document are solely those of the recipient, and do not necessarily reflect those of the Agency. EPA does not endorse any products or commercials services mentioned in this publication.

16. Coordination/Communication after Grant Award:

After award, the CEMALB will have regular (suggested monthly) meetings with EPA management and key scientists to exchange ideas, review progress, propose new projects, and other information. All proposed cooperative research projects between EPA and CEMALB scientists will be reviewed and approved by this group.

Science Advisory Committee (SAC) - After award, the Center must establish a SAC. The SAC membership will typically consist of peers selected from the academic, private, non-profit, and public sectors as well as at least one EPA representative. The function of the SAC is to assist in evaluating the (1) merit, value and contribution of the Center's projects, and (2) relevance and importance of the individual research elements to accomplishing the overall goals of the Center. The SAC will review CEMALB activities every two years and prepare an integrated report describing their views on the progress made by the CEMALB as well as suggestions for changes in direction, if appropriate.

17. Agency Contact

Further information, if needed, may be obtained from the EPA contact indicated below:

Steve Jackson (jackson.steve@epa.gov)