Science to Achieve Results (STAR) Program
National Center for Environmental Research
U.S. Environmental Protection Agency

PARTICULATE MATTER RESEARCH CENTERS

This is the initial announcement for this program.
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SUMMARY OF PROGRAM REQUIREMENTS

Synopsis of Program:
The U.S. Environmental Protection Agency (EPA), as part of its Science to Achieve Results (STAR) program, seeks applications for Particulate Matter Research Centers to study priority issues related to airborne particulate matter, including susceptibility, mechanisms of health effects, exposure-response relationships, and source linkages. Centers will be funded for up to five years. A total of up to $8 million is available for the first year to support this effort at this time.

Award Information:
Anticipated Type of Award: Grant
Estimated Number of Awards: Up to 5
Anticipated Funding Amount: Up to $40 million
Cost Sharing: None Required
Potential Funding per Grant: Up to $1,600,000 per year for up to 5 years, and no more than a total of $8,000,000, including direct and indirect costs. Proposals with budgets exceeding the total award limits will not be considered.

Eligibility Information:
Institutions of higher education and not-for-profit institutions located in the U.S., and Tribal, state and local governments, are eligible to apply. See full announcement for more details.

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INTRODUCTION

The U. S. Environmental Protection Agency announces an extramural funding competition for Particulate Matter Research Centers to address priority research needs related to airborne particulate matter, including susceptibility, mechanisms of health effects, exposure-response relationships, and source linkages. This announcement provides relevant background information, summarizes EPA's interest in supporting these Centers, and describes eligibility requirements and application instructions for the program.

Information regarding current research can be found on the Office of Research and Development's National Center for Environmental Research (NCER) homepage at http://es.epa.gov/ncer/science/pm.

BACKGROUND

While the United States has made noticeable progress over the last four decades in reducing air pollution, substantial concern remains about the health effects of ambient particulate matter (PM), a major component of the air pollution mix in many areas of the country. Time series studies in numerous cities, as well as recent multi-city studies, show associations between daily mortality and changes in PM_{10} and $PM_{2.5}$ (EPA 1996, Samet et al. 2000a, Dominici et al. 2002). Prospective epidemiological studies reported significant associations between an increased risk of premature mortality and long-term exposure to $PM_{2.5}$ (Dockery et al. 1993, Pope et al. 1995). These results were confirmed in extensive reanalyses and new analyses indicating premature

mortality included not only cardiopulmonary causes, but cancer as well (Krewski et al. 2000, Pope et al. 2002). Elevated levels of PM have also been linked to various indices of morbidity, ranging from hospitalization for respiratory or cardiovascular diseases to moderate exacerbation of respiratory diseases or decreases in lung function (EPA 1996, Pekkanen et al. 1997, Linn et al. 2000, Samet et al. 2000a, Heinrich et al. 2000, Peters et al. 2001). Some population subgroups are more susceptible to the effects of PM than others. Observational studies have shown that people older than 65 years of age have higher mortality risks associated with PM exposure than the population as a whole (EPA 1996). Individuals with pre-existing cardiovascular or respiratory disease show similar or higher risk of PM-related mortality and morbidity (EPA 1996, Goldberg et al. 2000, Samet et al. 2000b, Zanobetti et al. 2000). Other disease states, such as diabetes, may also increase an individual's PM-related risk (Goldberg et al. 2001, Zanobetti and Schwartz 2001, Zanobetti and Schwartz 2002,). There is recent evidence on suppression of lung growth during childhood, and limited evidence suggesting prenatal effects of PM (and perhaps co-pollutants) (Jedrychowski et al. 1999, Gauderman et al. 2000, Avol et al. 2001, Gauderman et al. 2002, Ritz et al. 2002).

Recent toxicological and controlled human exposure studies provide biological plausibility for the health effects observed in the epidemiology studies as well as mechanistic hypotheses to describe how PM may exert its effects (Ghio et al. 2000, Lambert et al. 2000, Brook et al. 2002, Campen et al. 2002, Utell et al. 2002, Kodavanti et al. 2003, Lippmann et al. 2003). Some of these theories are quite complex and involve interaction between several organs or tissues (e.g., lung, heart, vascular system, autonomic nervous system). As PM is a complex mixture of many different components, it is possible that different components stimulate different mechanistic pathways or interact in other ways to alter response mechanisms. Thus, exposure to PM may result in one or more pathways being activated depending on its chemical and physical makeup.

Considerable progress has been made in understanding the relationship between measurements of PM from ambient monitors and the concentrations to which people are actually exposed. This research has been important in the interpretation of epidemiological studies that use ambient monitoring data to estimate exposure. Studies show that $PM_{2.5}$ easily penetrates into most indoor environments, where people spend much of their time. While the strength of the correlation may vary by season and location, recent studies in the eastern U.S. have found that ambient measures of $PM_{2.5}$ reasonably represent personal exposure to $PM_{2.5}$ (Williams et al. 2000, Sarnat et al. 2001, Williams et al. 2002).

Unlike most pollutants, ambient PM varies by chemical composition and size (ultrafine, fine, coarse, and larger) depending upon the particle formation processes. This leads to significant variability in PM characteristics across time and space, across source categories, and across individual sources within a single source category. Although a few air quality areas may have a PM character strongly influenced by a single source (e.g., a large power plant or smelter), PM for most air quality areas results from a mixture of locally generated emissions and those transported in from distant sources that are distinguished by high spatial and temporal variability (NARSTO 2003). A further complication exists in that any given individual particle can differ appreciably from another individual particle within a given size range.

Previous research and measurements from the national $PM_{2.5}$ monitoring network confirm that $PM_{2.5}$ composition varies by region (Tolocka 2001). The eastern US typically has higher levels of sulfate $PM_{2.5}$. The western US generally has higher amounts of crustal and nitrate $PM_{2.5}$ (EPA 2001, EPA 2002). Both eastern and western US locations observe significant levels of organic $PM_{2.5}$, which contains thousands of individual chemical species that are poorly characterized (Turpin 2000, Schauer 2002, Zheng 2002). Other potential regional differences include the relative contribution of diesel and gasoline vehicles, coal and oil burning, the importance of secondary organic aerosol, and the proximity to large industrial sources of $PM_{2.5}$ (NARSTO 2003). Characterization of regional differences in composition and emission sources provides insight for design of health effects studies and emission control strategies.

In 1997, EPA revised the national ambient air quality standards (NAAQS) for PM to add new standards for fine particles ($PM_{2.5}$), as well as retaining standards for PM_{10}. In subsequent litigation, the Court ruled against the use of PM_{10} as an indicator for coarse fraction particles since PM_{10} includes $PM_{2.5}$. EPA is now addressing coarse-fraction particles by considering standards using $PM_{10-2.5}$ as an indicator, referring to particles with a mean aerodynamic diameter greater than 2.5 μm but less than or equal to 10 μm.

To implement the 1997 standards, EPA has conducted nationwide ambient PM monitoring, and by the end of 2004 will determine which areas of the country have failed to meet the standards. After these designations are made, State, local and tribal agencies will develop and implement plans to attain the standards. Many of the eastern states and specific portions of the western U.S. are expected to be affected.

Also in 1997, Congress asked EPA to arrange for an independent study by the National Academy of Sciences, National Research Council (NRC), to identify priorities for a comprehensive PM research plan, to recommend a near- and long-term PM research program, and to monitor research progress over the next five years across the federal government. The NRC panel identified ten PM research priorities and reviewed research progress in a series of reports (NRC 1998, 1999, 2001). The final report assesses progress on the research agenda, synthesizes key research accomplishments in PM science, updates the Committee's research recommendations, and serves as a valuable resource to all applicants. It emphasizes the need to examine PM from a multidisciplinary perspective to better address the complex nature of PM that cuts across clearly defined scientific specialties (NRC 2004).

A number of federal agencies have come together to coordinate efforts on PM research, through the Air Quality Research Subcommittee of the Committee on Environment and Natural Resources (CENR). CENR has issued a strategic plan (CENR/AQRS 2002) for coordinated PM research by participating federal agencies. In addition, NARSTO, the North American public-private atmospheric science research consortium, has just completed an assessment of atmospheric science supporting national standard attainment and identified future research needs (NARSTO 2003).

Based on recommendations from the NRC reports, the CENR/AQRS strategy, the NARSTO assessment and EPA's own internal research planning process (EPA 2003), EPA developed and

is implementing an integrated research program for PM. It involves the coordinated efforts of intramural and EPA-funded extramural investigators and partners, as well as other federal organizations, within a scientific framework of research needs developed by the NRC committee of experts. The program reflects the integration of multiple disciplines including exposure and health effects research, atmospheric science and air quality engineering.

RESEARCH CENTERS

In appropriating fiscal year 1998 funds, Congress urged EPA to establish as many as five university-based research centers focused on PM research. EPA issued a competitive request for applications (RFA) in 1998, and awarded five-year grants to five PM research centers in 1999. These Centers are now completing their fifth year of work.

This RFA is a new competition for PM Research Centers. It is open to both new Center applicants and existing PM Research Centers. All applications will be evaluated by an external peer review panel convened by NCER's Peer Review Division. Subsequently, the most highly rated applications will be considered by EPA scientists and managers in order to select the next set of Centers that will best address the key research issues identified in this solicitation.

This RFA includes a description (below) of the research needs which the PM Research Center applicants will address. These needs are broad, reflecting a cross-cutting theme of linking health effects with PM from source categories and components. EPA recognizes that not every applicant will address all of the topics specified in the RFA. However, the most critical science questions faced by the Agency's PM research program are multidisciplinary in nature.

The most successful applicants will take an integrated approach that addresses in a scientifically sound manner aspects within the continuum of PM sources to effects. Applicants are required to demonstrate how the various projects contained within their proposals are fully integrated, encourage participation of investigators with the most appropriate expertise, and employ cutting edge approaches. In contrast with individual grant awards that focus on a specific research question, PM Centers present the opportunity for investigators from different disciplines to work together on larger problems than could be addressed in a single grant proposal. An example of such integration might include atmospheric scientists and health scientists working together to better understand the kinds of PM emitted from a source category, changes in PM composition over time or geographical distance, and the health effects associated with exposure to them. Applicants should focus proposals on the science questions in which the applicant has demonstrated expertise rather than extending beyond core strengths simply to address many topics. Proposed Centers may include arrangements which bring together institutions with strengths in different disciplines provided they can demonstrate how effective integration in planning and implementing research will be achieved.

Centers may be funded for up to five years; applications should clearly show how the program might evolve during that time. A successful application will recognize that PM research priorities must evolve as new data are generated and will include a detailed description of the process by which the Center will set priorities and phase in new activities, as appropriate. An

iterative process might be used, for example, in which interpretation of new results in health studies will influence subsequent studies in exposure and source apportionment, the results of which may influence further health studies. The process should lead to a better understanding of the source-concentration-exposure-dose-response continuum.

RESEARCH NEEDS

The NRC has published four reports that recommend and discuss a portfolio of research activities targeted to address the highest priority PM research needs (NRC, 1998, 1999, 2001, 2004). Since the expanded investment in PM science by Congress in 1998, progress has been made in many areas of PM research, by EPA's intramural research laboratories, through EPA's grants and centers programs, and through other research programs. To identify the areas of focus for this RFA, EPA has evaluated the NRC research priorities, the CENR/AQRS PM research strategy, the NARSTO PM Assessment, the EPA Science Advisory Board's interim review of the PM research centers (EPA Science Advisory Board 2002) and considered the research activities currently underway. This RFA emphasizes priority research areas needed to promote scientific understanding of the linkages between sources, PM components and physicochemical attributes, exposure and health effects. Through this RFA, the Agency is soliciting proposals to develop research centers which construct well-defined and integrated programs that address PM research needs in the areas of susceptibility, mechanisms of health effects, exposure-response relationships, and source linkages.

SPECIFIC AREAS OF INTEREST

Cross-Cutting Theme: Linking Health Effects with PM from Sources and Components

In its 1998 report, and reiterated in 2004, the NRC PM committee described a source-to-response framework. This framework continues to provide a useful structure for identifying and organizing PM research priorities.

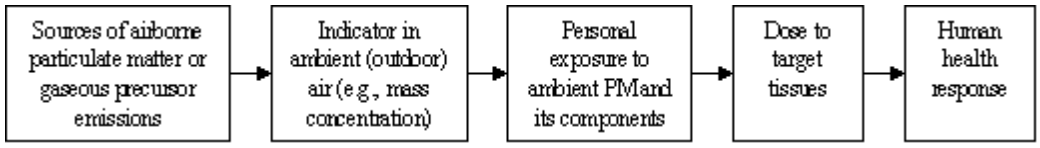

Fig. 1 Source-to-response continuum (adapted from NRC 1998 and NRC 2004)

This RFA relies on the source-to-response continuum as a cross-cutting theme to facilitate the integration of PM research proposals. EPA research continues to address the health effects of PM characteristics and constituents, but increasingly, key research questions are focusing on linking these PM attributes to source categories. Research is needed to understand relationships between PM components/attributes emitted from emission sources and the resulting ambient concentrations and human exposures. Research is also needed to understand the relative toxicity of different PM components/attributes, and to link these back to emission sources and exposures.

Collectively, this information can help identify those sources and attributes of PM contributing to the most hazardous exposures.

As emphasized by the NRC Committee in its final report, some progress has been made in identifying specific attributes or chemical components of PM, but there are still critical gaps in our understanding of the contribution of PM components (e.g., organic compounds) and attributes (e.g., different size fractions of PM) to the observed health effects associated with PM (NRC 2004). Studies are encouraged that lead to a better understanding of health effects caused by different physical characteristics of particulate matter (e.g., coarse, fine and ultrafine size fractions) or by aspects of the physical chemistry of PM. Also of interest are studies which link health effects with variations in exposure or response related to PM components, such as organic carbon, elemental carbon, and inorganic components such as sulfates, nitrates and metals. Additionally, studies are encouraged which address PM alone or in combination with co-pollutants such as ozone, nitrogen and sulfur oxides. Of particular interest are studies which determine if these interactions are additive or synergistic in nature, along with characterizing the resulting adverse health effects and underlying mechanisms of such interactions.

Specific Topics

Described below for each priority research area is a brief overview of the research needs which the PM Centers, in toto, are anticipated to address. The proposed projects and integrated application should indicate how the research will contribute to improved understanding of key elements of the continuum from sources through PM components/attributes to health effects.

Susceptibility to PM

Increasing our understanding of who is susceptible to the effects of PM, and why they are susceptible, will improve the scientific basis for air quality standards and will aid in the development of strategies for minimizing the effects of PM on these susceptible groups. With the understanding that PM can act systemically, rather than only impacting the lungs, emerging evidence is suggesting there may be specific susceptible populations other than those already identified. Additionally, certain windows of vulnerability (e.g., fetal development, people with viral infections) may increase susceptibility (Zanobetti et al. 2000, Ritz et al. 2002). Some studies have suggested that other factors, such as socio-economic status, race, or gender may play a role in susceptibility to PM-related effects, but only limited and inconsistent evidence on such groups is available (Abbey et al. 1999, Pope et al. 2002). In addition, long term exposure to PM may move an individual into a susceptible "pool" where acute exposures to multiple stimuli (e.g., tobacco smoke, pathogens, paint fumes, other air pollutants) could cumulatively induce adverse health effects. Furthermore, different components or other PM attributes may target people with different susceptibilities (e.g., people with asthma may be especially susceptible to biologic components present in PM).

To address the questions of susceptibility, proposals may employ any number of approaches including *in vitro*, animal, controlled human exposure, panel studies, small clinical studies, and epidemiologic studies. This RFA encourages novel application of appropriate animal models,

including naturally susceptible, disease-induced, and genetically or pharmacologically manipulated models. The innovative use of *in vitro* models is also encouraged.

Research Question: What subpopulations are at increased risk of adverse health outcomes from exposure to PM of different compositions or from different sources? What are the factors that make individuals more susceptible to PM?

Specific issues of interest include:

- What previously-unrecognized subpopulations are susceptible to PM-induced health effects?
- What are the personal factors (e.g., disease state, diet, genetics, socio-economic status) that influence susceptibility to effects of PM? Are these personal factors different for acute versus chronic exposure to PM?
- How do these factors contribute to making "healthy" people permanently or temporarily susceptible to the adverse effects from exposure to PM?
- What underlying biological mechanisms are responsible for effects in susceptible populations? (see Mechanisms topic below).
- Do certain subpopulations have unique PM component exposures by virtue of personal factors and what is their impact?

Biological Mechanisms for PM

The mechanisms by which PM, or other air pollutants, cause adverse health effects are not yet adequately understood. PM consists of many different components, and size fractions, all of which may affect health outcome by different mechanisms. In addition, PM affects different organ systems and is likely to cause adverse effects in these systems by different mechanisms. Finally, it is likely that the underlying mechanisms for acute and chronic effects are different.

For the purpose of this RFA, 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 PM. For example, studies which describe changes in heart rate variability or pulmonary inflammation induced by PM exposure would not be considered mechanistic; but studies which characterize the underlying processes responsible for changes in heart rate variability or pulmonary inflammation would be considered mechanistic.

This RFA promotes novel application of appropriate animal models, including naturally susceptible, disease-induced, and genetically or pharmacologically manipulated models. The innovative use of *in vitro* models is also encouraged. The use of state-of-the-art molecular biology, genetic and genomic, proteomic, and metabolic profiling techniques to address these questions is equally encouraged.

Research Question: What are the underlying biological mechanisms that can explain specific

health effects associated with exposure to PM and/or specific PM components?

Examples of specific areas of interest include:

- What are the physiological, cellular, biochemical, molecular mechanisms by which PM causes acute and/or chronic adverse health effects?
- Do different PM components, or PM derived from various sources, cause adverse health effects by different mechanisms? How do the mechanisms differ?
- How are the mechanisms that underlie health effects observed following exposure to high concentrations of PM different from mechanisms responsible for effects following exposure to low concentrations of PM?
- How are the mechanisms which underlie the response of susceptible animals or humans different from those which occur in healthy individuals?

Exposure-Response Relationships

Epidemiological studies have established that exposure to ambient PM is associated with adverse health effects (EPA 1996), but much remains to be learned about the nature of PM exposure-response relationships. In understanding PM exposures, researchers have made progress in identifying correlations between central site measurements of ambient PM mass and personal exposure to total, ambient, and nonambient PM, and information is emerging on the key factors that affect these correlations (Williams et al. 2000, Williams et al. 2002, Liu et al. 2003). However, it is not clear whether these correlations are also true for individual PM components or attributes. Better understanding of personal PM exposures is needed to improve exposure assessment models used in epidemiological studies of PM effects.

Questions remain about how differences in duration of PM exposure affect its impact. For example, short term spikes of high duration (a few hours) may cause more adverse health effects than longer exposures to lower PM concentration, even though the amount of PM deposited during a 24 hour period may be similar. Additionally, much of the PM health research to date has focused on effects reported in daily time series studies or in animals or humans acutely exposed to PM. Research on health effects associated with long-term exposure to PM is more limited. EPA is currently funding several large epidemiological studies examining the effects of long-term exposure to PM and therefore is not seeking additional studies of this type. However, smaller-scale epidemiological analyses that offer new insights may be of interest. Similarly, toxicology studies which characterize the effects of long term exposure in animals are appropriate, especially if they can lead to a better understanding of susceptibility and mechanisms.

Research is also needed to establish the relationships between personal exposure, dose and response, for a range of exposure conditions. Better information is needed on issues such as high dose to low dose extrapolations, and dose-response curves which enable estimations of the proportion of the population expected to experience adverse health effects, depending on their exposure pattern, ventilation, and susceptibility.

To address questions related to exposure-response relationships, proposals may include a wide range of study approaches, including exposure modeling, animal toxicology, small clinical or panel studies, and epidemiologic studies. Approaches which develop improved exposure assessment for panel or epidemiologic studies are encouraged.

Research Question: What are the exposure-response relationships for the biologically important constituents/sizes of PM and PM from different sources?

Specific areas of interest include:

- What are the relationships between ambient concentrations of PM, its attributes, constituents, and co-pollutants, and personal exposures to ambient and non-ambient PM and co-pollutants? How do human activities, population demographics, housing characteristics, and/or local sources affect personal exposure to ambient PM?
- How are responses to PM affected by duration of exposure (e.g., short-term peak exposures vs. 24 hour exposures) or spatial/temporal variability in PM concentrations?
- What are the effects of long-term (weeks, months, years) exposure to PM?
- What is the shape of the exposure-response function for PM across a concentration gradient that includes ambient exposure levels? How does it vary for different health endpoints and for PM and its constituents/attributes derived from various sources?

Source Linkages

Evidence from numerous toxicological studies has indicated that the type and strength of adverse health effects due to exposure to ambient PM vary as the attributes of PM change (Costa and Dreher 1997, Kodavanti et al. 1998, Clarke et al. 2000, Nel 2001, Oberdorster 2001, Saldiva 2002). The attributes that have been studied in most detail are particle size and composition, both of which often vary with particle source, and often with the atmospheric conditions through which particles are transported and transformed. Understanding the generation of particles, how these attributes may be changed (or formed from precursor gases) between the point of emission and the point of exposure, and the relative contributions of sources to the ambient PM concentrations in different regions of the country, is important for understanding the links between emissions and local air quality and the links between sources and adverse health effects associated with exposure to PM.

Not only do particle attributes vary with source type, but impacts on composition and size result from changes in design or operation of sources within a source type. For instance, changes in engine design over the past decade have resulted in diesel engines that have very different emissions characteristics (including particle attributes) compared to earlier engine designs. In addition, the mode of operation also impacts the size and composition of particles, whether from open vegetative burning (Hays et al. 2001), mobile source engines (Brown et al. 2000), or stationary utility and industrial sources (Miller and Linak, 2002). To better understand the links

from source through atmospheric transformation and exposure to dose and effects, it is necessary to tie the key particle attributes (including, but not limited to, size distribution, organic species, metal content, and bioavailability of particle species) to specific source types, including across different designs and operating conditions.

In addition to understanding the attributes of particles associated with specific sources, it is also necessary to better understand the contribution of source categories to the mix of particles in the ambient atmosphere and ultimately to the particles to which people are exposed. While previous source apportionment efforts have largely focused on source categories that contribute the most PM mass, the importance of some smaller mass sources may increase when considering health effects.

Studies of the health effects caused by ambient particles are of higher value when the sources of those samples can be estimated using methods such as source apportionment. These often require a more thorough understanding of the composition of ambient, personal, and source samples, including levels of specific species within those samples. Proposals are encouraged that improve our understanding of the processes that link sources and receptors in such a way that the impact of specific source types or particle attributes on health effects may be more completely understood.

Research Question: What are the relationships between emissions sources and ambient concentrations of particulate matter, its components and size fractions?

Specific issues of interest include:

- How do changes in source design or operation impact the attributes of emitted, and ultimately ambient, PM?
- How can the relationships among emission sources, atmospheric concentrations, and personal exposures to ambient PM be understood and represented in different methods and models?
- How do atmospheric processes in different regions of the country influence ambient concentrations and the source-receptor relationships that impact observed air quality levels and health effects?
- How can methods that link sources and receptors be applied to better understand the contribution of source types, components, and attributes to air quality levels and health effects?
- How can health responses to ambient PM exposure be linked to specific emission sources and/or source categories?

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SPECIAL REQUIREMENTS

For the Application

Each application should address the following (For general application information and list of page limitations, see the section below on "Submitting an Application"):

1. Center Description: Applications should describe the overall goals, objectives, and approach for the Center, including how the Center will pursue a multi-disciplinary and thematic approach to the problems to be investigated (5 page limit).

2. Project Descriptions: Applications should describe projects that address one or more of the research areas described above. Each of the specific individual research projects should be completely described according to the Standard Instructions for Submitting a STAR Application, Section 2, Research Plan. Individual project descriptions must explain how the project fits into the overall Center program and relates to other projects in the proposal (15 page limit for each project description).

3. Administrative Core Unit: Each Center shall have an Administrative core unit which provides overall oversight, coordination and integration of the Center's Activities. As part of the Administrative Core description, applications should provide a Center Integration Plan describing how the program will be integrated internally. Center proposals should take a multi-disciplinary approach. The Center's Integration Plan, at minimum, should indicate how programmatic and funding decisions will be made; how new projects will be solicited, reviewed and selected; how investigators from different disciplines within the Center will communicate on a regular basis about the development and progress of Center projects; how progress will be monitored; who sets priorities, and who is responsible for implementing the integration plan, assuring compliance with the plan, and evaluating its effectiveness in achieving integration within the Center (15 page limit).

The Center proposal should also address how the Center will disseminate research findings and other information. Publishing research results in scientific journals is essential, however, it is not sufficient. Plans for Center websites and other means of communicating results should be described.

Additional responsibilities of the Administrative Core include (as described below under "After Grant Award"): coordination and integration among Centers, organization of Scientific Advisory Committee meetings and development of responses to SAC recommendations.

4. If appropriate and desired, a Center may elect to have one or more facility support cores that provide a technique, service, or instrumentation that will enhance ongoing research efforts across the Center's specific projects. Examples of such facilities are analytical chemistry laboratories, statistics centers, laboratory animal facilities, etc. The application must provide a compelling rationale for why such a core is needed and how it will be used by multiple projects within the proposed center (15 page limit per Core).

5. In conducting its research, the Center must demonstrate a willingness to use, as appropriate, existing or future air quality data bases, especially relating to PM, as they become available. In addition, the Centers are encouraged to seek out and participate collaboratively with ongoing/planned intensive air quality monitoring efforts.

After Grant Award

These instructions supplement the section in the Standard Instructions entitled "Expectations and Responsibilities of STAR Grantees." After the grants are awarded, the Centers will work with the EPA Project Officers to address the following:

1. Integration Among Centers - According to EPA's Science Advisory Board in its review of the PM Centers program, "There is a clear need for and benefit from increased inter-Center interaction...The Centers program should stimulate and facilitate collaboration within and between the five Centers, with the goal of harmonizing designs, methods of measurement, and analysis..." Experience with the first PM centers underscored the notion that integration among the Centers enhanced scientific understanding and research productivity. Integration among Centers requires significant commitment, time and effort.

Within three months of the award, the PM Centers will form a PM Centers Committee that will consult monthly to exchange ideas, research needs, protocols, and other information. The group will identify research areas that would benefit from harmonization, joint workshops, sharing of data, samples, expertise or technologies. One example, emphasized by the NRC in its most recent report (2004), would be a systematic approach to assessing toxicity of PM mixture components. EPA anticipates that the PM Centers Committee will discuss and act on some areas of shared interest, and that subcommittees will be formed as needed to address more specialized topics. EPA scientists will help organize and participate in joint working groups as appropriate.

2. Communications - Centers are expected to develop and maintain Center web sites, communicate key findings at annual scientific conferences, and participate in annual EPA investigators meetings. The Centers will each produce annual progress reports and a final report at the end of the grant period. Throughout the five year period, project summaries and final results will be provided in a format compatible with broader efforts to compile and synthesize the large amounts of information on PM. In addition, the Centers are expected to cooperate in the production of an integrated, interim report of progress midway through the grant cycle and a final report of findings at the conclusion of the grant.

3. Administrative Contact - Each Center will identify an individual to be the main point of administrative contact with the EPA project officers. This person will be responsible for ensuring that information on human subjects, animal welfare, Center publications, press releases, progress reports, quality assurance, science advisory committees and other documentation is provided to the project officer in a timely fashion.

4. Science Advisory Committees - After award, each Center must establish an external science advisory committee (SAC) that can provide objective, independent, technical advice to the Center to ensure scientific quality and progress. The SAC membership will typically consist of nine to twelve peers selected from the academic, private and public sectors and an EPA representative(s). The function of the SAC is to assist in evaluating the (1) merit, value and contribution of existing and future research projects, and (2) relevance and importance of the individual research elements to accomplishing the overall goals of the Center. Within 90 days of the award, the Principal Investigator must submit a list of nominees for the SAC to the Project Officer for approval by EPA. Potential SAC members must NOT be contacted, identified, or queried prior to receipt of the award.

Each PM Center will hold a meeting with its SAC annually. Upon receiving the written recommendations from the SAC, the PM Center director shall submit a formal letter to EPA and the SAC chair with its response to the SAC comments and a plan for how the Center will implement improvements.

MECHANISM OF SUPPORT/FUNDING

It is anticipated that a total of up to $40 million will be awarded, depending on the availability of funds. EPA anticipates funding up to 5 grants under this RFA. The projected award per grant is $1.3 to $1.6 million per year total costs, for up to 5 years. Requests for amounts in excess of a total of $8 million, including direct and indirect costs, will not be considered. The total project period for an application submitted in response to this RFA may not exceed 5 years. Funding in subsequent years will be contingent upon satisfactory progress.

ELIGIBILITY

Institutions of higher education and not-for-profit institutions located in the U.S., and Tribal, state and local governments, are eligible to apply. Universities and educational institutions must be subject to OMB Circular A-21. Profit-making firms are not eligible to receive grants from EPA under this program.

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.

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 principal investigator, but may not direct projects on behalf of the applicant organization or principal investigator. The principal investigator's institution, organization, or governance may provide funds through its grant from EPA to a 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 a grant, and may not receive salaries or in other ways augment their agency's appropriations through grants made by this program. However, federal employees may interact with grantees so long as their involvement is not essential to achieving the basic goals of the grant. EPA encourages interaction between its own laboratory scientists and grant principal investigators for the sole purpose of exchanging information in research areas of common interest that may add value to their respective research activities. This interaction must be incidental to achieving the goals of the research under a grant. Interaction that is "incidental" does not involve resource commitments.

The principal investigator's 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, along with an assurance from the federal agency involved which commits it to supply the specified service.

Potential applicants who are uncertain of their eligibility should contact Tom Barnwell in NCER, phone 202-564-0824; As of April 5, 202-343-9862; email: barnwell.thomas@epa.gov

COST-SHARING

Institutional cost-sharing is not required.

SUBMITTING AN APPLICATION

Sorting Code
The need for a sorting code to be used in the application and for mailing is described in the Standard Instructions for Submitting a STAR Application. The sorting code for applications submitted in response to this solicitation is 2004-STAR-H1.

Standard Instructions for Submitting an Application

The Standard Instructions for Submitting a STAR Application including the necessary forms will be found on the NCER web site, http://es.epa.gov/ncer/rfa/forms/downlf.html. **However, the following page limitations supercede those in the Standard Instructions:**

Page Limitations

The following page limitations may not be exceeded:

Abstracts -	1 page abstract for the Center as a whole; and, 1 page abstracts for each proposed project

Research Plan - 5 pages for overall Center objectives, approach, and expected benefits
15 pages for each research project description

Research Cores - 15 pages for the Administrative Core
15 pages for each additional Core

Budget - Budget summary pages and project pages should include both annual budgets for each year, one through five, and cumulative totals for the entire five year period:
2 page summary for total Center budget
2 pages per project
2 pages per Administrative and other Cores

Budget Justification - 2 pages per project
2 pages per Administrative and other Cores

Quality Management -5 pages

Quality Management Plan

For any project involving data collection or processing, conducting surveys, environmental measurements, modeling, or the development of environmental technology (whether hardware-based or via new techniques) for pollution control, the EPA requires a plan discussing processes that will be used to assure that results of the research satisfy the intended project objectives. The required plan is described below. This requirement for a brief Quality Management Plan (QMP) replaces the requirement "2.J. Quality Assurance Statement" in the Standard Instructions.

EPA is particularly interested in the quality controls for data generation and acquisition, and how data validation and usability will be verified. The Statement must describe a system that complies with ANSI/ASQC E4, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, and must not exceed five consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins. ANSI/ASQC E4 is available for purchase from the American Society for Quality, phone 1-800-248-1946, item T55. Only in exceptional circumstances should it be necessary to consult this document.

The QMP provided with the application must contain the shown information below. EPA's Quality System will likely require an expanded version of this document following award.

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

2. Organization and Management - This section should include:
A) Organization chart that identifies:
– all of the components (research project or core activity) of the Center;

– the Principal Investigator or overall manager for each component;
– the person responsible for QA/QC activities for each component and how they report to the QA Manager and Center Director;
B) Description of the specific responsibilities of the QA Manager and any other personnel with QA responsibilities;
C) Description of any delegations of QA responsibility to sub-awardees or contractors (especially QC responsibilities); and
D) Discussion of how the Center will maintain effective communications throughout the management structure.

3. Quality System - This section should include brief discussions of:
A) How the Center's research activities will be reviewed and evaluated to ensure quality;
B) How staff will be trained, and who is responsible for training;
C) How data will be stored and made available to Center personnel and to the public; and
D) How the Center's QA/QC procedures will be reviewed and evaluated, including how recommended changes will be implemented.

4. Project or Component Specific - This section should discuss the QA and QC needs for the Center's components and should describe or reference any standard procedures (such as SOPs) that will be used to address these needs. (Individual project QA plans, expected after award as part of the Center's QA program, should include descriptions of how the data needs relate to the hypotheses being tested or the objectives.) This section should also address the following:
A) How the sample size(s) will be selected and demonstrated to be sufficient to test the hypotheses or meet a specific objective;
B) How the necessary performance criteria for measured data to test the hypotheses or meet the objective will be identified;
C) How the quality of previously collected data will be determined appropriate for its stated use;
D) How data will be managed (collected, backed-up, collated, transferred, and stored) to ensure that the quality is maintained and documented; and
E) What data analysis methods will be used.

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

Note: Congress, through OMB, has instructed each agency to implement Information Quality Guidelines designed to "provide policy and procedural guidance . . . for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies." EPA's implementation may be found at http://www.epa.gov/oeiinter/qualityguidelines/index.html . These procedures may apply to data generated by grant recipients if those data are disseminated as described in the Guidelines.

APPLICATION PROCESSING AND REVIEW INFORMATION

Applications must be received by the application receipt date listed in this announcement. If an application is received after that date, it will be returned to the applicant without review.

The following is the schedule for this RFA. It should be noted that this schedule may be changed without notification due to factors that were not anticipated at the time of announcement.

Application Receipt Date: August 31, 2004
Earliest Anticipated Start Date: July 1, 2005

Peer Review and Criteria

This section replaces "Section 6.B. Peer Review and Criteria" in the Standard Instructions. In general, the peer review group will be composed of non-EPA scientists and engineers who are experts in their respective disciplines and are proficient in the technical subjects they are reviewing. Reviewers are asked to assign a summary score to the application of either excellent, very good, good, fair, or poor, and use the criteria below to help them in their evaluations. The first two criteria are of highest importance, the remainder are listed in descending order of importance.

1. Overall Center
Centers must include research projects with a conceptual theme focusing on one or more of the research areas outlined in the RFA. There must be evidence of the potential for a meaningful interdisciplinary collaboration between all of the components of the program.

> Interdisciplinary nature of the proposed research activities, integration of the projects around an overarching theme, and plans to effectively pursue interdisciplinary research objectives.
>
> Potential impact of the research in achieving a better understanding of the health effects associated with sources and components of particulate matter
>
> Capacity of the projects to result in a greater contribution to the overall goals of the Center than if each were pursued independently.

2. Research Projects
Reviewers will be asked to evaluate each proposed research project using the criteria listed in the STAR Standard Instructions and repeated here:

The originality and creativity of the proposed research, the appropriateness and adequacy of the research methods proposed. Is the research approach practical and technically defensible, and can the project be performed within the proposed time period? Will the research contribute to scientific knowledge in the topic area? Will the results be disseminated broadly to enhance scientific and technological understanding? What may be the benefits of the proposed activity to society? Is the proposal well-prepared with supportive information that is self-explanatory or understandable?

The qualifications of the principal investigator(s) and other key personnel, including research training, demonstrated knowledge of pertinent literature, experience, and publication records.

Will all key personnel make a significant time commitment to the project?

The responsiveness of the proposal to the research needs identified for the topic area. Does the proposal adequately address the objectives specified by the EPA for this topic area?

The availability and/or adequacy of the facilities and equipment proposed for the project. Are there any deficiencies that may interfere with the successful completion of the research?

3. Administrative and Other Cores
Scientific and organizational structure of the Center. Are the lines of authority and administrative structure designed for effective Center management? How does the administrative structure maximize the Center's capability to take advantage of research opportunities?

Qualifications, responsibilities, and effectiveness of senior leaders. The Principal Investigator/Center Director should be an established research scientist with the ability to ensure quality control and the experience to administer effectively and integrate all components of the Center. Is the percent effort appropriate?

Duties and percent efforts of administrative staff of the center in terms of their qualifications and contributions to the specialized needs and conduct of the center's research activities.

Effectiveness of the center's internal planning and quality management activities. Who is involved and what mechanisms are used? Are these activities documented?

Nature and quality of facility cores, if proposed. Technical merit, justification, cost effectiveness, qualifications of staff, utility to investigators, and arrangements for internal quality control, allocation of resources, priority of usage, and day-to-day management.

4. Budget

Although budget information does not reflect on the application's scientific merit, the reviewers are asked to provide their view on the appropriateness and/or adequacy of the proposed budget and its implications for the potential success of the proposed research. Input on requested equipment is of particular interest.

CONTACT POINTS

Further information, if needed, may be obtained from one of the EPA officials indicated below.
Stacey Katz, Phone 202-564-8201; As of April 5, 202-343-9855; email: katz.stacey@epa.gov
Gail Robarge, Phone 202-564-8301; As of April 5, 202-343-9857; email robarge.gail@epa.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 66.509.

The authority for this RFA and resulting awards is contained in Clean Air Act, Section 103, as amended, Public Law 95-95, 42 U.S.C. 7401 et seq.