

ABSTRACT

The Administration and Research Coordination Core will provide oversight, coordination and integration of the Center's activities within and between projects at Harvard University, the University of Toronto, and the University of Michigan, and also with EPA and the other PM Centers. The Administration and Research Coordination Core will be responsible for administration and organization, fiscal management, research management, research integration, research co-ordination, and communication.

The Center Directors will be responsible for the overall administration and management of the Center. They will work in close collaboration with the Steering Committee consisting of the Research Project and Core leaders. An external Science Advisory Committee will provide annual review and guidance on progress and priorities. Research integration will be achieved through regular meetings of a Working Group on PM Health Effects, a PM Work in Progress Seminar, a PM Journal Club, and PM Workshops. In addition, research activities will be integrated across the PM Centers through regular Director's teleconferences and annual meetings of the Consortium of EPA PM Centers.

A major strength of the current Center's program is the ability to redirect research to respond to recent findings and specific EPA needs. Thus we have in place a system to continually review and redirect Center research. The Center Steering Committee will continuously monitor research progress and developing research issues. The Center Investigators will present results and progress annually to the external Science Advisory Committee and will seek guidance on research priorities. In this application we present five proposed research projects which have been defined by this process as providing cutting edge approaches to a central topic, that is, the pathways and effects of exposures to particles from the different sources. Each of these projects will be monitored and evaluated for progress and relevance, and may be modified or replaced over the five years of Center support.

The final objective of the Center is to make the results of this research available through peer-reviewed scientific publications, but also to communicate these results in a fashion accessible to policy makers and the lay public. To this end we present Center results in scientific conferences, hearings and other public forums, and maintain a web-site which presents these results in a clear fashion and provides links to detailed results.

1. OBJECTIVES

The objective of the Administration and Research Coordination Core is to provide overall oversight, coordination and integration of the Center's activities within and between projects at Harvard, the University of Toronto (St. Michael's Hospital), and the University of Michigan, and also with EPA and the other PM Centers. The Administration and Research Coordination Core will be responsible for:

- administration and organization;
- fiscal management;
- research management;
- research integration;
- research coordination, and;
- communication.

Each of these activities is described in the following sections.

2. APPROACH

2.1. Center Administration and Organization: The Administration and Research Coordination Core is responsible for all administrative activities including administrative, secretarial, and fiscal management; central data management and quality assurance; organizing working group meetings, seminars, and Science Advisory Committee meetings; preparation of progress reports, and; communication with EPA and other institutions. We have defined a hierarchical organizational structure consisting of the Center Directors, a Center Steering Committee, and an external Science Advisory Committee.

2.1.1. Center Directors and Administrative Contact: Dr. Petros Koutrakis will serve as Director of the EPA PM Center and will oversee all scientific aspects of the Center. Dr. Douglas Dockery (Center Deputy Director) will oversee all administrative and fiscal issues for the Center and will work closely with the Center Director. The Deputy Center Director will be assisted by Alice Smythe, who will be appointed as the Center Staff Assistant. The Center Director and Co-Director will be responsible for administration and management of the Center research, for facilitating interactions and collaborations between Center investigators, and fostering collaborations with investigators outside the Center at Harvard, other local research institutions, other PM centers, and EPA. They are responsible for organizing and running monthly meetings of the Steering Committee, annual meetings of the Science Advisory Committee, and seminars and meetings of Center investigators. They will also serve on the PM Centers Directors Committee and represent the Center at scientific meetings and public hearings.

Dr. Dockery will serve as the primary administrative contact with the EPA project officers. Dr. Dockery will also 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 EPA project officers in a timely fashion.

2.1.2. Center Steering Committee: The Center will be overseen by a Steering Committee consisting of the Center Director (Dr. Koutrakis), the Deputy Center Director (Dr. Dockery), the Financial Director (Ms. Linda Fox), the Principal Investigators of the Research Projects, (Drs. John Godleski, Joel Schwartz, Helen Suh, and Frances Silverman), and the Directors of the Cores (Drs. Brent Coull and Philip Demokritou). The Steering Committee will meet monthly at Harvard to monitor research progress, to review research initiatives within the Center and outside of the Center, and to manage operations. The University of Toronto (Dr. F. Silverman) and University of Michigan (Dr. R. Brook) members will generally participate by telephone teleconference, but may also be linked by videoconference. Steering Committee meetings will be held in the Exposure, Epidemiology, and Risk conference room at Harvard, which is fully set up for video-conferencing, with up to four outside participants.

2.1.3. Science Advisory Committee: A multi-disciplinary Science Advisory Committee of nine distinguished scientists (six non-governmental and three from EPA or other government agencies) will be established to provide input into both on-going and future research directions. The Advisory Committee will be comprised of experts in a range of disciplines, including Exposure Assessment, Atmospheric Chemistry, Epidemiology, Toxicology, Biostatistics, Cardiac and Respiratory Health, Risk Assessment, and Public Policy. Some committee members will be recruited from other PM Centers to foster and facilitate exchange and collaborations.

The Committee will meet annually for two days to review formally the Center activities. The first meeting day will be devoted to the traditional presentation of study designs and results. This will be followed by a structured workshop on the second day to define research needs and priorities. This workshop will include both the Committee members and the Center investigators.

The members of the Science Advisory Committee will select a Chair at their first meeting. Following each SAC meeting, the Chair will be responsible for soliciting comments from the SAC members, and preparing a written report to the Center Director, with a copy to the EPA Project Officer. Within three months of receiving the written recommendations from the SAC, the Center Director will submit a formal letter to the EPA Project Officer and the SAC Chair, with a response to the SAC comments, and a plan for how the Center will implement recommendations.

2.2. Fiscal Management: All fiscal administrative duties will be directed by Ms. Linda Fox, Administrator of the Exposure, Epidemiology and Risk Program. She will provide quarterly budget summaries and projected expenditures. Ms. Fox will work with Joan Stulac, Administrative Manager, at the Gage Occupational & Environmental Health Unit (of St. Michael's Hospital and the University of Toronto) and John Burnett at the University of Michigan, in fiscal management of these subcontracts. Ms. Fox and Dr. Koutrakis will be responsible to the Assistant Dean for Administration of the Harvard School of Public Health, Mr John Lichten, for overall fiscal administration of the program.

2.3. Research Management: Research management of the Center includes data management, quality assurance, and compliance with regulations regarding the use of humans and vertebrate animals in research.

2.3.1. Data Management: The research staff at Harvard University has considerable experience working with large exposure, epidemiological, and toxicological data sets. While the Principal Investigators are responsible for processing and analyzing data for their individual projects, data from each of the projects are stored and managed centrally, with Martha Fay responsible for Health Data Management, and James Sullivan responsible for Exposure Data Management. Bruce Urch will be responsible for Data Management at the University of Toronto, and will transmit data generated in this project to Ms. Fay and Mr. Sullivan in a timely manner.

The Data Managers provide centralized expertise and resources for management, quality control, quality assurance, storage, and access to Project and Core data. The Data Managers provide centralized data tracking, processing, quality assurance procedures, and documentation management. Finally, the Data Managers ensure that data are accessible to Center investigators in a timely fashion, through a centralized, shared-access study database with regular back-up and archiving. The Data Managers receive and compile standardized progress reports of data collection and processing from each of the Projects and Cores for review at the regular meetings of the Center Steering Committee.

2.3.2. Quality Assurance: Each research project has an identified Quality Control liaison (see Quality Management Plan). These project specific QC liaisons report to the independent Center QA/QC Officer, Jose Vallarino, who reports directly to the Center Director, Dr. Koutrakis. Mr. Vallarino is a Senior Scientist at the Exposure, Epidemiology and Risk Program and has considerable experience preparing and reviewing laboratory and field protocols and quality control procedures. He is the QA officer for the current EPA PM Center and has worked extensively with the EPA Project Officers for these Centers.

2.3.3. Human Studies: Each research project using human subjects will obtain individual review and approval from the Harvard School of Public Health Human Subjects Committee, as well as approval from Institutional Review Boards of the St. Michael's Hospital (University of Toronto), the University of Michigan, and other collaborating institutions. The Toronto group has over 30 years of human exposure experience, including 8 years of experience with Concentrated Ambient Particles (CAPs) exposures. The Administration and Research Coordination Core maintains records of Human Studies review and compliance. In addition, the Administration and Research Coordination Core ensures that all staff in contact with human subjects or identifiable subject data have received appropriate Human Studies and HIPAA training, and maintain records of this training. Mr. Jose Vallarino is the Center human subject protocol coordinator and works closely with the Human Subjects committees, the project investigators and EPA project manager.

2.3.4. Vertebrate Animals: The Center assures humane practice in animal maintenance and experimentation, and subscribes to the concept of using every acceptable method in the performance of Center research to minimize the use of animals and to prevent animal distress. Each project involving vertebrate animals will individually obtain protocol approval from the Harvard Medical Area Standing Committee on Animals. The Administration and Research Coordination Core maintains records of Vertebrate Animal Studies review and compliance.

Veterinary and diagnostic services are provided by the Animal Resources Center at the Harvard School of Public Health. The Harvard School of Public Health is accredited by the American Association for the Accreditation of Laboratory Animal Care, and meets National Institutes of

Health standards as set forth in the "Guide for the Care and Use of Laboratory Animals" (DHEW Publication No. [NIH] 78-23 Revised). The Standing Committee on Animals periodically reviews the care and treatment of animals in all Harvard School of Public Health animal facilities to assure compliance with law and good laboratory practice.

The principal investigator, laboratory personnel, and animal technicians involved in any way in the proposed research will have instruction or demonstrated competence in the care, use, and handling of laboratory animals. The Administration and Research Coordination Core maintains records of certifications.

2.4. Center Research Integration: The Administration and Research Coordination Core is responsible for fostering collaboration and integration of the PM research conducted by the Center, and collaboration and integration with EPA and the other Centers. We integrate this research through our Working Group on PM Health Effects and through the Consortium of EPA PM Centers.

2.4.1. Working Group on PM Health Effects: We have an established Working Group on PM Health Effects that meets weekly to foster informal interactions among the Center investigators and interactions with other PM investigators at Harvard. This Working Group was formed about eight years ago and includes experts in exposure and risk assessment, epidemiology, toxicology, clinical medicine, and physiology. The proposed EPA PM Center will expand this Working Group to include PM investigators at the University of Toronto and the University of Michigan, and will provide Core support for Working Group activities. In addition to the weekly meetings, these activities include bi-monthly series of informal Work-In-Progress Seminars, a PM Journal Club, and PM Workshops (all described below).

2.4.1.1. Working Group Weekly Meetings: The PM Working Group has met weekly on Tuesday mornings for approximately eight years. Major advances have been made as a result of the informal interactions among the investigators working on exposures, controlled animal, and human epidemiology studies.

For example, results of observational epidemiologic studies presented at these weekly meetings led to the design animal CAPs inhalation studies of diseased animal models. These laboratory studies not only provided validation of the epidemiological findings, they also generated specific hypotheses regarding the effects of particles on the cardiac health for testing in human epidemiologic studies. Subsequent panel studies of elderly found associations between heart rate and heart rate variability and particle exposures, confirming the results from laboratory studies. Because of the close collaboration between the toxicology and particle chemistry groups, we now have preliminary results regarding the association between particle health effects and specific constituents of fine particulate matter.

During the development of this proposal for a PM Center, the University of Toronto and University of Michigan investigators participated in these weekly meetings by phone teleconference, using the NetMeeting service of our onsite video-conference facility.

2.4.1.2. Multi-disciplinary Research in Toronto: The research group in Toronto, including collaborators from Michigan, is a multi-disciplinary team that has worked together on numerous PM projects. This multi-disciplinary approach has allowed for extensive cross-over between departments in the larger academic community – generating a multitude of perspectives and expertise in research design and evaluation.

The Toronto and Michigan research team members actively participate in the seminars sponsored by each other's departments. These seminar programs include those organized by the Gage Occupational & Environmental Health Unit (Dr. Frances Silverman), Meteorological Services of Canada (Dr. Jeffrey Brook), and the University of Toronto's Respiriology Division (Dr. Frances Silverman). This form of research communication has contributed to the creation of new collaborations and to fostering existing relationships that have led to the development of novel techniques to study air pollution. The Toronto/Michigan group is now composed of researchers in the pulmonary, cardiovascular, and atmospheric sciences, occupational and environmental health, chemistry and chemical engineering.

Recently, the Toronto group, through funding from the Canadian Foundation for Innovation, has helped pioneer SOCAAR – the Southern Ontario Centre for Atmospheric Aerosol Research – a unique group of health professionals, environmental engineers, and atmospheric chemists. SOCAAR-funded infrastructure, including ultrafine and coarse particle concentrators to be installed in the Toronto exposure facility in collaboration with Harvard, will play a prominent role in the proposed human study

2.4.1.3. PM Work in Progress Seminars: Under the auspices of the PM Working Group and with direct support from the Center, we hold a bi-monthly PM Work in Progress seminar on Friday mornings. Each Center investigator informally presents their research at least once each year. This seminar also provides a forum for other PM researchers at Harvard and the affiliated institutions to present their work. In addition, we use this forum to bring in experts from outside the Boston community to present their work. This year invited outside speakers have included Dr. Robert Brook of the University of Michigan, Dr. Bert Brunekreef of the University of Utrecht, and Dr. Wayne Cascio of the University of North Carolina. We will bring the University of Toronto and University of Michigan investigators to present their research at Harvard at least once per year.

These seminars are open to the public, and are advertised through an e-mail list and are posted on the Center website and the Harvard School of Public Health Calendar. Attendance averages approximately 25 per session, and includes investigators, students and fellows from Harvard Schools of Public Health and Medicine, the affiliated hospitals, Harvard College, MIT and the Health Effects Institute. We will make these Work in Progress Seminars available to the University of Toronto and University of Michigan investigators by videoconferencing. These seminars are organized by Drs. Dockery and Godleski.

2.4.1.4. PM Journal Club: In the upcoming academic year, we will use one of the other Friday time slots each month for a PM Journal Club. The Journal Club will be a forum for students, fellows, and investigators to keep up-to-date on PM research outside of the PM Center. Each Center investigator will lead at least one journal club meeting per year. They will select a paper to be discussed and lead the review. Dr. Dockery will organize this effort.

2.4.1.5. Between Center PM Workshops: Periodically the EPA PM Center will partner with other research groups, including other PM Centers, for joint workshops. In September of 2002 we held a two day joint PM Workshop in North Carolina with investigators from EPA, NIEHS, the University of North Carolina, and Duke University. Seventeen PM researchers from Harvard participated, including faculty, research associates, post-doctoral fellows, and pre-doctoral students, along with 25 PM researchers from the RTP area. Discussion was organized around Breakout Sessions about ongoing research activities, methods and approaches, and

opportunities for collaboration and sharing resources. This Workshop led to multiple new initiatives including:

- Assess induced sputum as a biomarker of exposures to particles (UNC) ;
- Comparison of fine, coarse and ultrafine concentrators for animal and human exposure studies (EPA);
- PUF particle samples for toxicology studies (EPA);
- Elemental carbon analysis of Six Cities filters (EPA);
- Standardized assessment of endothelial dysfunction (UNC), and;
- Analyses of blood and serum samples from epidemiologic studies (EPA).

We propose to conduct similar joint PM Workshops with other PM Centers and/or EPA research centers.

2.4.2. Consortium of EPA PM Centers: As one of the current EPA PM Centers, we participate in the Consortium of PM Centers. This Consortium attempts to ensure that research in each Center is coordinated with, complementary, and not redundant with that of other Centers. It also facilitates rapid dissemination of research findings and other information between Centers, the EPA, the rest of the scientific community, and the lay public.

To achieve these specific aims, the Consortium has an annual meeting open to all investigators from all Centers and EPA scientists. These annual meetings rotate between, and are hosted by individual Centers. There is a planning committee for each Consortium meeting with representatives from each Center, which defines a set of research questions to be addressed at the meeting. Center investigators present recent results or current research activities which are relevant to these pre-defined questions. There is also a meeting of the Center Directors only, to coordinate research activities and discuss issues common to all the Centers. Through the Consortium, the EPA Centers have established linked sites on the World Wide Web to provide descriptions of current research programs, downloadable copies of research reports and publications, and access to extended summaries and original data.

In addition, there is a Center Director's teleconference at least every month. These teleconferences provide a forum for discussing administration, collaborative research, and new initiatives. These teleconferences have also been used to prepare reports and publications describing the overall work of the Centers¹.

2.5. Center Research Coordination: A key aspect of the ongoing and proposed Center is the continual evaluation of research needs and priorities. To achieve this goal, the current Center has implemented a rigorous and multi-phased research coordination and evaluation process. This coordination and evaluation process draws on experts from a wide range of disciplines at the Harvard School of Public Health and also from experts from outside agencies, universities, and other organizations, to provide focused and timely responses to current and evolving questions about airborne particulate matter. Specifically, experts from four internal and external groups will contribute to the research coordination and evaluation process and will determine the direction and coordination of PM research that is conducted at the Center. These groups include: 1) the External Science Advisory Committee; 2) the Consortium of EPA Airborne Particulate Matter Centers; 3) the Working Group on PM Exposures and Health Effects, and; 4) the current PM Center Steering Committee.

There is a plethora of external factors which in the past had an impact on our Center research activities, for example:

- Research findings from other EPA Centers or other research groups;
- Research recommendations from national and international panels, e.g., from the National Research Counsel committee;
- Scientific disputes on important PM issues which could have an impact on rule-making, e.g., GAMS, and;
- Comments from our peers about our research through direct contact or through the peer review processes.

Decisions are based on several criteria, including: scientific progress of the research, relevance, innovation, opportunities, leveraging, scientific value, and timing. We have a two-step process for making adjustments to our research activities. First, we seek consensus among the Center Investigators on the Steering Committee. Second, we seek the opinion and consent of the Center Science Advisory Committee. We believe that between our own highly qualified group of investigators and the external advisors we are able to make appropriate decisions regarding the future direction of the Center.

The decision for terminating an existing project, partially or entirely, is a challenging one. A project may be terminated or modified for different reasons, such as: successful completion; lack of productivity; lack of human or material resources, or; need to divert resources and focus attention on new areas of engagement. EPA Centers are dynamic entities which may adjust their research portfolios as needed. As an existing PM Center, we have used this flexibility to terminate some research projects. For example two years ago we terminated Center Project IIIb, entitled “Particle Dosimetry”, based on the recommendation of our Science Advisory Committee, which urged us to focus more on biological mechanisms rather than animal dosimetry.

The decision for initiating a new project is exciting because researchers always generate new ideas which they would like to pursue. However, resource availability and relevance of the proposed project to the mission of the Center are important issues, which should be addressed prior to engaging into a new research activity. Two years ago we initiated the Toxicological Evaluation of Realistic Emissions of Source Aerosols (TERESA): Application to Coal-Fired Power Plant-Derived PM_{2.5}, which was not included in our original Center proposal. Due to the limited available funds, this study was co-sponsored by EPRI. To date, this investigation has generated some exciting preliminary findings, thus we have decided to include this study in this proposal. This may make possible its continuation and expansion to mobile sources. The process for the initiation of this study was a simple one. First, the idea was discussed among the Center PIs, and then it was presented to our Science Advisory Committee.

2.5.1. Integration Between Harvard, Toronto and Michigan: A strong attribute of this PM Center proposal is that it anticipates capitalizing on academic relationships that have formed over the years between Harvard PM investigators and PM investigators in Toronto and Michigan. These relationships date back to the joint development of a human CAPs exposure facility in Toronto in 1996, and to more recent collaborations to look at specific PM health outcomes such as heart rate variability. In recognition of the similar PM research interests of Harvard, Toronto, and Michigan, investigators from each of the groups have also presented research results to each other as invited speakers on numerous occasions.

In the current proposal, all three groups will work closely on a novel study of fine, ultrafine and coarse CAP exposures in humans (Project 3). This study will be supervised by Dr. Frances Silverman (Principal Investigator) of Toronto. Drs. Robert Brook (Co-Investigator) of Michigan and Diane Gold (Co-Principal Investigator) of Harvard, are the key personnel who will provide additional scientific expertise. These main investigators will communicate regularly via monthly conference calls, and additionally, as needed. The study manager, Mr. Bruce Urch, will also have access to all communication to ensure the transition between input from Harvard, Toronto, and Michigan on high level issues, to the day-to-day operation of the study. Furthermore, as outlined above, Toronto and Michigan co-investigators will present research updates annually for evaluation by the Scientific Advisory Board and the other project PIs, and they will also participate in the evaluation of other projects.

2.6. Center Communications: An important function of the Center is the dissemination of research findings and other information. Clearly, publishing research results in scientific journals is essential, as these peer-reviewed articles provide the basis for standard setting. However, there is a larger need to communicate results of Center research in a way that is accessible to the lay community and other non-scientists. In addition, there is a need to participate in public discussion of Center research through presentations and testimony before regulatory and governmental agencies and boards. To this end, the Center will communicate the research findings through scientific publications, presentations, the Center Website, and progress reports.

2.6.1. Scientific Publications: The primary form of communications is through publication of original research in the peer-reviewed scientific literature. The current EPA PM Center has a record high productivity with 70 published articles in the past four years (Figure 1). In addition to original research, the Center investigators have published three reviews and commentaries supported by the Center.

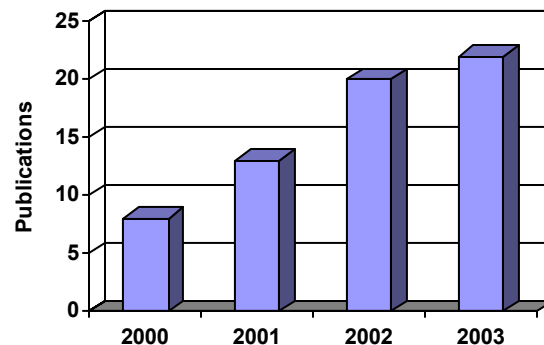


Figure 1. Harvard/EPA PM Center original research peer-reviewed publications.

2.6.2. Center Website: The current PM Center maintains a website (<http://www.hsph.harvard.edu/epacenter/>) which describes the research objectives, ongoing studies, and other activities. The website provides a listing of all published scientific articles supported by the Center. There is a “hot link” to each article, so the full text can be viewed by users. The website provides links to the other PM Centers as well as other resources for information on PM research and policy.

In addition we provide a monthly synthesis of new results in layman’s language, including the “hot links” to these publications. There is also a calendar of upcoming research seminars sponsored by the Center which are open to the public.

2.6.3. Presentations: In addition to formal publication of research results, the Center investigators will communicate key findings at annual scientific conferences. For example, there were 12 presentations²⁻¹³ specifically acknowledging current PM Center support at the recent International Society of Environmental Epidemiology Meeting (Aug 1-4, 2004, New York), and four will be presented at the upcoming International Society of Exposure

Assessment Meeting (October 11-17, 2004, Philadelphia). We will also participate in the annual Consortium of EPA Center Investigators' meetings and other Center organized public meetings. The calendar on the Center website will list upcoming presentations at scientific conferences and public meetings by Center investigators.

2.6.4. Progress Reports: The Center will provide annual progress reports and a final report at the end of the grant 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 proposed Center will cooperate with the other EPA Centers in the production of an integrated, interim report of progress midway through the grant cycle and a joint final report of findings at the conclusion of the grant.

3. REFERENCES

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