

State of California
AIR RESOURCES BOARD

Resolution 02-32

December 12, 2002

Agenda Item No.: 02-9-5

WHEREAS, the Air Resources Board (Board) has been directed to carry out an effective research program in conjunction with its efforts to combat air pollution, pursuant to Health and Safety Code sections 39700 through 39705;

WHEREAS, asthma is a continuing and growing public health problem in California, affecting the lives of children and adults afflicted with this disease;

WHEREAS, a major objective of the Air Resources Board is to protect the health of the public, including infants and children, from the adverse effects of air pollution;

WHEREAS, a major focus of the Air Resources Board's health research is to determine the role of air pollution in creating new asthma cases, causing asthma attacks, and affecting the long-term health of those already afflicted with asthma;

WHEREAS, a research proposal, number (2522-226), entitled "Fresno Asthmatic Children's Environment Study (FACES) Proposal: Project Period 2," has been submitted by the University of California, Berkeley;

WHEREAS, this study is an essential element of the Board's research program to determine the health impacts of air pollution on vulnerable populations, including asthmatic children;

WHEREAS, the Research Division staff has reviewed and recommended this proposal for approval;

WHEREAS, the FACES External Advisory Panel, composed of leading national health and exposure scientists, has reviewed and recommends this proposal for funding;

WHEREAS, the External Advisory Panel, as part of their review, discussed and commented in detail on the critical issues affecting the success of this study and found that the study, as developed, would have adequate statistical power to identify health outcomes;

WHEREAS, the Research Screening Committee has reviewed and recommends this proposal for funding;

Proposal Number (2522-226) entitled "Fresno Asthmatic Children's Environment Study (FACES) Proposal: Project Period 2," submitted by the University of California, Berkeley, for a total amount not to exceed \$2,396,389.

NOW, THEREFORE BE IT RESOLVED, that the Air Resources Board, pursuant to the authority granted by Health and Safety Code section 39703, hereby accepts the recommendation of the FACES External Advisory Panel and the Research Screening Committee and approves the following:

Proposal Number (2522-226) entitled "Fresno Asthmatic Children's Environment Study (FACES) Proposal: Project Period 2," submitted by the University of California, Berkeley, for a total amount not to exceed \$2,396,389.

BE IT FURTHER RESOLVED, to ensure that the study continues to rely on advice from the best scientific experts in the field, that the staff of the Research Division will coordinate annual meetings of the FACES External Advisory Panel, a workshop of coordinators from the Fresno and Los Angeles "PM Supersites" and their associated health studies by summer of 2003, and quarterly meetings between the Fresno "PM Supersite", Air Resources Board staff, and FACES aerometric data managers;

BE IT FURTHER RESOLVED, that the University of California, Berkeley investigators will keep the study enrollment period open to accommodate possible additional enrollees from the Kaiser Health System, and are encouraged to apply to the National Institute of Environmental Health Services for funding to complete the study in case monies are not available next fiscal year from the Air Resources Board due to the State's fiscal situation;

BE IT FURTHER RESOLVED, staff will report back to the Board by February 2004 on the performance of the University of California, Berkeley investigators in meeting the conditions described above, and the availability of funding to complete the study;

BE IT FURTHER RESOLVED, that the Executive Officer is hereby authorized to initiate administrative procedures and execute all necessary documents and contracts for the research effort proposed herein, and as described in Attachment A, in an amount not to exceed \$2,396,389.

I hereby certify that the above is a true and correct copy of Resolution 02-25, as adopted by the Air Resources Board.

Stacey Dorais, Clerk of the Board

ATTACHMENT A

“Fresno Asthmatic Children’s Environment Study (FACES) Proposal: Project Period 2”

Background

FACES is the first study to be sponsored under the Vulnerable Populations Research Program. The project was originally presented to and approved by the Research Screening Committee in November 1999 and the Board in January 2000. At that time the first phase of the project was funded, with funding for the second phase contingent on satisfactory progress during the first phase. The rationale and objectives for the original proposal, to examine the potential impact of air pollution on the natural progression of asthma, have not changed. Asthma is a growing problem in California. Over 2,200,000 California residents have asthma. Fresno County was chosen as the site of this study since it is an area notable for a very high prevalence of asthma among children, the area has an ethnically diverse population, and the area suffers from frequent high levels of ambient air pollution, especially particulate matter (PM) and ozone air pollution.

FACES will address critical needs for information on the potential impacts of air pollution on asthmatic children. This study is an essential part of the Vulnerable Population Research Program, which was specifically designed to examine the health impacts of air pollution on particularly susceptible populations. Asthma has a profound impact on the lives of the children and adults afflicted with this disease. A major objective of the Air Resources Board is to protect the health of the public, particularly infants and children, from the adverse health impacts of air pollution. Part of this objective involves the Air Resources Board’s research program to examine the effects of air pollution on the health of asthmatics, which may be more sensitive to air pollution’s adverse impacts.

In California, as elsewhere, the prevalence of asthma appears to be increasing. Outdoor air pollution has not been strongly implicated in the increase of new asthma cases; however, there is compelling evidence that asthmatics are especially susceptible to acute responses when exposed to ambient air pollutants. Little is known about the relationship between exposure to the different components of PM and acute responses among asthmatics. Even less is known about the acute effects among asthmatics resulting from complex gaseous and particle air pollution exposures, or from potential interactions of air pollutants with other known airborne asthma triggers such as pollens, mold spores, or endotoxin. Lastly, little data exists on the relationship between the long-term effects (disease progression) of repeated air pollution exposures and short-term acute responses. This study will address these data gaps, providing new information on the impact of air pollution on asthma. FACES is essential to provide the Board with critical information needed to develop regulations to protect one of California’s most sensitive populations, asthmatic children.

Review by External Advisory Panel

At the recommendation of the ARB's Research Screening Committee, at the onset of this study an External Advisory Panel was formed to advise the investigators in conducting the study and to advise the ARB regarding the progress of the study and recommendations for the continuance of the study. The External Advisory Panel is composed of leading national health and exposure scientists who meet and review the progress of the study on an annual basis. The annual meeting of the Panel was canceled in 2002 due to schedule conflicts and only a small subset of the Panel met in May 2002 to discuss the study. In June 2002, the Panel was sent copies of the study's Interim Report and the proposal for Project Period 2 for their review and comment. However, only a few Panel members provided comments. At the Board's directive for a full airing of issues related to the smaller-than-expected enrollment of children into the study, the Panel met by teleconference on November 20, 2002. All members of the Panel were able to attend the teleconference.

At the teleconference, the External Advisory Panel discussed their review of the study and the Project Period 2 proposal. Panel members commented in detail on the critical issues affecting the success of this study. Among those critical issues are the impact of the smaller children's sample size on the ability of the study to determine long-term health effects in asthmatics. The three statisticians on the Panel presented their individual comments on the study protocols and unanimously concluded that the statistical power calculations were reasonable and concluded that the study has adequate power. The External Advisory Panel found that subject retention and health data quality were higher in this study in comparison to others and to some degree offset the reduction in sample size. The External Advisory Panel concluded by unanimously recommending ARB to continue full funding for the study.

Objective

FACES is designed to examine the acute and chronic health effects of particle air pollution, in combination with other ambient air pollutants and bioaerosols, on children with asthma residing in Fresno County, California. The primary objectives stated in the proposal are to:

- 1) Determine the relationship between short-term exposure to specific size fractions or constituents of particle air pollution, or other ambient air pollutants, and acute exacerbations of asthma, which may include changes in lung function, occurrence of symptoms, and medication usage.
- 2) Identify the critical exposures leading to the observed acute health effects (e.g., determine the concentrations at which the effects occur); identify interactions with other outdoor and indoor pollutants (criteria pollutants, toxic air contaminants) or bioaerosols (pollens, spores, endotoxins); and identify specific sources of PM that may be more strongly associated with specific adverse effects.
- 3) Determine if repeated acute responses to short-term air pollution exposures have cumulative effects, such as altered disease progression (e.g., asthma severity) or changes in other markers of health status (e.g., reduced lung function growth).
- 4) Determine, in a sample from the general population of asthmatic children, the biologic characteristics (e.g. asthma severity, genetics, nutrition) or exposure

characteristics (e.g. activity patterns, housing characteristics) that define subgroups that are more (or less) responsive to a given acute exposure or set of exposures, or that experience larger effects associated with long-term exposures.

The exposure assessment portion of the study is designed to accurately estimate the daily exposure of the study participants, while the health component collects detailed health and activity information on the children, including but not limited to reports of symptoms, daily measures of lung function, and use of asthma medication.

Methods

The study consists of a variety of measurements taken over the course of five years. In the first year, an in-person baseline interview is conducted at the research site and includes skin testing for allergies, lung function testing and extensive questions about the child's health and home environment. Shortly thereafter, research staff visit the child's home to collect information during a period of time called a panel visit. During the 2-week panel visits, children are given diaries to record their activities and the time they spend in different locations throughout the day. They are also asked to provide information on their asthma symptoms and medication usage, as well as to perform lung function tests with portable instruments called spirometers. Measurements of indoor air and dust are also taken at the participant's residence during the panel visits. The air inside of the participant's home and the dust are tested for environmental tobacco smoke, nitrogen dioxide, and allergen content during all panel visits. For a subset of the participants, more extensive monitoring is being conducted inside and outside of their homes, focusing on several components of PM.

After the first panel visit, participants are alternately contacted by phone and interviewed in person at three-month intervals to gain additional information about recent health care utilization and changes in medication use. Each participant takes part in 2-week panel visits approximately every six months.

Expected Results

The depth and quality of air pollution measurements, exposure estimation, and detailed health evaluations in this 5-year study will provide critical insights into the role of specific air pollutants and other environmental factors in acute responses and the natural history of childhood asthma. FACES will answer several remaining questions regarding the association between exposure to air pollution and exacerbation of asthma. These questions include the relationship between symptom and lung function responses to short-term fluctuations in air pollution and the natural history of asthma, identifying the specific components of the mix of ambient air pollutants that may be responsible for the health effects seen, and determining the optimal pollutant-specific metrics for the evaluation of health effects.

Significance to the Board

The FACES study will provide essential information to assist the Air Resources Board and other regulatory agencies to develop appropriate air quality standards and regulatory actions to protect the health of one of Californian's most sensitive

populations, asthmatic children. The findings will help health care providers identify children who are at the greatest risk for adverse effects of air pollution and guide decisions about environmental and medical interventions. The combination of community level action and individual level action can lead to improvements in the protection of this highly vulnerable subgroup (i.e., asthmatic children), and to significant reductions in the direct and indirect asthma-related costs borne by all Californians.

Contractor:

University of California, Berkeley.

Contract Period:

February 2003 - August 2005

Principal Investigator (PI):

Dr. Ira Tager

Contract Amount:

\$2,396,389

Cofunding:

none

Basis for Indirect Cost Rate:

The State and UC System have agreed to a ten percent indirect cost rate.

Past Experience with this Principal Investigator:

This study is being conducted by an experienced team of investigators from the School of Public Health at the University of California, Berkeley. The team is led by Dr. Ira Tager, an experienced epidemiological investigator. The investigative team includes Dr. Kathleen Mortimer, whose experience includes epidemiological studies of asthmatic children in low-income areas on the East Coast. The exposure assessment team is led by Dr. Katherine Hammond, whose experience includes studies on exposure to environmental tobacco smoke. Finally, Kathy Butler, who is based in Fresno area, heads the recruitment team. Ms. Butler has put together a program that has not only recruited children to participate in the FACES study, but has also been able to retain those participants at levels much higher than seen in other epidemiological studies.

Prior Research Division Funding to University of California, Berkeley :

Year	2001	2000	1999
Funding	\$957,698	\$1,588,071	\$2,220,519

BUDGET SUMMARY

Contractor: University of California, Berkeley

Asthmatic Children's Environment Study (FACES) Proposal: Project Period 2

DIRECT COSTS AND BENEFITS

1.	Labor and Employee Fringe Benefits	\$	1,405,063 ¹
2.	Subcontractors	\$	398,069 ²
3.	Equipment	\$	8,200
4.	Travel and Subsistence	\$	61,731
5.	Electronic Data Processing	\$	-0-
6.	Reproduction/Publication	\$	8,487
7.	Mail and Phone	\$	34,550
8.	Supplies	\$	56,023
9.	Analyses	\$	-0-
10.	Miscellaneous	\$	<u>241,877</u>
	Total Direct Costs		<u>\$2,214,000</u>

INDIRECT COSTS

1.	Overhead	\$	182,389
2.	General and Administrative Expenses	\$	-0-
3.	Other Indirect Costs	\$	-0-
4.	Fee or Profit	\$	<u>-0-</u>
	Total Indirect Costs		<u>\$182,389</u>

TOTAL PROJECT COSTS

\$2,396,389

¹There are 24 investigators total on this project.

²There are three subcontractors and one consultant included in this project.

Subcontractors:

Sonoma Technology Inc. (STI) (\$294,051). STI will coordinate the air pollution data collection from the homes, and will lead the development and implementation of the models to estimate personal exposure from measurements made at the central site, trailers, and in the homes of participants. STI offers personnel with expertise in working under the jurisdiction of the California Air Resources Board as well as expert knowledge in acquiring, implementing, merging, and analyzing air quality, meteorology, demographic, and health outcomes databases.

University of California, San Francisco (\$42,673). Dr. John Balmes from the University of California, San Francisco will work closely with the investigators on issues related to definitions of asthma severity, classification of medication use, and interpretation of lung function data. Dr. Balmes will participate actively in the analysis of the health effects data and in the preparation of manuscripts.

Technical & Business Systems (T&B Systems) Inc. (\$58,845). Dave Bush from T&B Systems Inc. provides external quality assurance for the project. He reviews all written protocols for data collection and data management, and provides feedback to the primary investigators. In addition, he audits all data measurement and management activities, and is responsible for ensuring that any necessary corrective action has been implemented.

Consultant:

Don Milton (\$2,500). Don Milton is internationally recognized as an expert in the analysis of endotoxin in the environment. He and his laboratory staff will consult with the investigators and will participate in quality assurance studies throughout the project. (Note: A separate Subcontractors' Budget Summary for this subcontractor is not included in this resolution due to the small amount of this subcontract, all of which is in labor.)

Attachment (1)

SUBCONTRACTORS' BUDGET SUMMARY

Subcontractor: Sonoma Technology Inc.

Description of subcontractor's responsibility: STI will coordinate the air pollution data collection from the homes, and will lead in development and implementation of the models to estimate personal exposure from measurements made at the central site, trailers, and in the homes of participants. STI offers personnel with expertise in working under the jurisdiction of the California Air Resources Board as well as expert knowledge in acquiring, implementing, merging, and analyzing air quality, meteorology, demographic, and health outcomes databases.

DIRECT COSTS AND BENEFITS

1.	Labor and Employee Fringe Benefits	\$	131,431
2.	Subcontractors	\$	-0-
3.	Equipment	\$	-0-
4.	Travel and Subsistence	\$	2,397
5.	Electronic Data Processing	\$	3,875
6.	Reproduction/Publication	\$	400
7.	Mail and Phone	\$	200
8.	Supplies	\$	150
9.	Analyses	\$	-0-
10.	Miscellaneous	\$	-0-

Total Direct Costs \$138,453

INDIRECT COSTS

1.	Overhead	\$	129,362
2.	General and Administrative Expenses	\$	-0-
3.	Other Indirect Costs	\$	-0-
4.	Fee or Profit	\$	26,236

Total Indirect Costs \$155,598

TOTAL PROJECT COSTS \$294,051

SUBCONTRACTORS' BUDGET SUMMARY

Subcontractor: University of California, San Francisco

Description of subcontractor's responsibility: Dr. John Balmes from the University of California, San Francisco will work closely with the investigators on issues related to definitions of asthma severity, classification of medication use, and interpretation of lung function data. Dr. Balmes will participate actively in the analysis of the health effects data and in the preparation of manuscripts.

DIRECT COSTS AND BENEFITS

1.	Labor and Employee Fringe Benefits	\$	38,794
2.	Subcontractors	\$	-0-
3.	Equipment	\$	-0-
4.	Travel and Subsistence	\$	-0-
5.	Electronic Data Processing	\$	-0-
6.	Reproduction/Publication	\$	-0-
7.	Mail and Phone	\$	-0-
8.	Supplies	\$	-0-
9.	Analyses	\$	-0-
10.	Miscellaneous	\$	-0-

Total Direct Costs \$38,794

INDIRECT COSTS

1.	Overhead	\$	-0-
2.	General and Administrative Expenses	\$	-0-
3.	Other Indirect Costs	\$	3,879
4.	Fee or Profit	\$	-0-

Total Indirect Costs \$3,879

TOTAL PROJECT COSTS \$42,673

SUBCONTRACTORS' BUDGET SUMMARY

Subcontractor: Technical & Business Systems (T&B Systems), Inc.

Description of subcontractor's responsibility: Dave Bush from T&B Systems, Inc., provides external quality assurance for the project. He reviews all written protocol for data collection and data management and provides feedback for the Primary Investigators. In addition, he audits all data measurement and management activities, and is responsible for assuring that any necessary corrective action has been implemented.

DIRECT COSTS AND BENEFITS

1.	Labor and Employee Fringe Benefits	\$	27,614
2.	Subcontractors	\$	1,800
3.	Equipment	\$	150
4.	Travel and Subsistence	\$	800
5.	Electronic Data Processing	\$	-0-
6.	Reproduction/Publication	\$	125
7.	Mail and Phone	\$	732
8.	Supplies	\$	700
9.	Analyses	\$	-0-
10.	Miscellaneous	\$	<u>-0-</u>
	Total Direct Costs		<u>\$31,921</u>

INDIRECT COSTS

1.	Overhead	\$	12,781
2.	General and Administrative Expenses	\$	8,793
3.	Other Indirect Costs	\$	-0-
4.	Fee or Profit	\$	<u>5,350</u>
	Total Indirect Costs		<u>\$26,924</u>

TOTAL PROJECT COSTS **\$58,845**