

North Dakota

Children's Health Study

Submitted to:

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The Industrial Commission
Lignite Research Program
600 East Boulevard Avenue
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Submitted by:

On behalf of:
North Dakota Children's Study Group
Whose membership consists of:
North Dakota Department of Health
Lignite Energy Council
Basin Electric Power Cooperative
Dakota Gasification Company
Minnkota Power Cooperative
Minnesota Power
Montana-Dakota Utilities Co.
Otter Tail Power Co.
Great River Energy

Funds Requested from the Industrial Commission of North Dakota

\$75,000

September 1, 1999

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North Dakota Children's Health Study

1.0 ABSTRACT

The North Dakota Department of Health (NDDH) and the Lignite Energy Council on behalf of Basin Electric Power Cooperative, Dakota Gasification Company, Minnkota Power Cooperative, Minnesota Power, Montana-Dakota Utilities Co., Otter Tail Power Co., and Great River Energy, hereafter identified as the sponsors, are requesting funding from the North Dakota Lignite Research, Development and Marketing Program to co-sponsor an epidemiological study that will assess the respiratory health of selected populations of North Dakota children. The study has three objectives:

1. Establish the prevalence rates of respiratory symptoms and asthma in kindergarten through sixth grade students living in "coal country" (McLean, Oliver, and Mercer counties), including the towns of Beulah, Hazen, Stanton, Washburn, Underwood, and Center.
2. Establish the prevalence of respiratory symptoms and asthma in kindergarten through sixth grade North Dakota students living in selected communities that are distant from lignite energy sources.
3. Compare the prevalence rates of respiratory symptoms, controlled for confounding factors, in the "coal country" students to the in-state comparison group. Compare the prevalence of respiratory symptoms to other published epidemiological studies.

The question of interest is whether, once indoor environmental factors and other potentially confounding factors are controlled for, the prevalence rates of asthma, bronchitis, chronic cough, wheezing, and chest illness will differ among the selected populations within the state. The rates in the two groups will also be compared to those in other U.S. populations studied with similar instruments. This initial study will not explore explanations for differences, should any be found.

John D. Spengler, Ph.D., Professor at the Harvard School of Public Health, and Jonathan Samet, M.D., Chair of the Department of Epidemiology, Johns Hopkins School of Hygiene and Public Health, are the principal investigators leading the epidemiological study team (EST) for the North Dakota Children's Health Study.

During an initial four month planning phase, the study questionnaire will be finalized, the comparison community selected, and arrangements made for data collection. Questionnaire administration is scheduled for the spring of 2000 preceded by four months of planning. Data analysis and report preparation will follow quality control checking of the field component and questionnaires. Results are scheduled to be available in the fall of 2000. Timelines for the study are detailed in Section 9.0.

Proposed funding for the study is \$75,000 from NDDH, \$75,000 from industry, and a grant match of industry funds of \$75,000 from the Lignite Research Development and Marketing Program (LRC). Funding will be used by the stakeholders (sponsors and LRC) to employ project staff, for project management, for contracting the epidemiological study team, for Advisory Panel (AP) expenses, for Technical Advisory Panel (TAP) expenses and for materials and miscellaneous expenses for the project.

2.0 PROJECT SUMMARY

The North Dakota Children's epidemiological study is designed to assess if significant and substantial differences in respiratory symptoms and morbidity, particularly asthma, occur in children living in proximity to coal-fired energy generating sources compared to children distant from these sources. The design specifications are to conduct a cross-sectional comparison of two groups, children from coal country and from a comparison set of communities. This proposal details the study approach, methodology, project background, and project goals.

The study will focus on elementary school-age children in grades kindergarten through six. Children of this age have been selected for several reasons. They can be readily studied in school and comparison studies are available. For the most part, they are beyond the age of highest susceptibility to respiratory infections and they spend substantial time outside. They also have few potentially confounding exposures, like cigarette smoking. In addition, the U.S. EPA and the National Institute of Environmental Health Sciences have recently emphasized the health of children in regulation and research.

Researchers from the Harvard School of Public Health and Johns Hopkins School of Hygiene and Public Health have been hired to develop methodology and to guide the epidemiological study. Input from the local community is essential for success of the study and the study planning will include active participation from the community. Members of the public health, medical, government, and education communities will serve as an Advisory Panel to the North Dakota Children's Health Study.

The study design will be carefully developed to identify potential confounding variables that might differ between the two groups. These confounding factors include but are not limited to housing conditions that may influence indoor air quality, involuntary tobacco smoke exposure, history of respiratory illnesses in family members, early childhood medical conditions, and the age and gender of the child.

The NDDH and the lignite energy industry will recommend possible communities distant from coal country to the EST for their recommendation prior to approval. "Coal country" populations will

consist of city and rural youth ... McLean, Mercer and Oliver counties who attend local schools. North Dakota is a frontier state and the potential limitation posed by a small sample size is a concern for the study. The sponsors will consider the statistical power of the epidemiological study prior to giving final approval.

3.0 PROJECT DESCRIPTION

3.1 Goals and Objectives

The project objectives are as follows:

1. Establish the prevalence rates of respiratory symptoms and asthma in kindergarten through sixth grade students living in "coal country" (McLean, Oliver, and Mercer counties), including the towns of Beulah, Hazen, Stanton, Washburn, Underwood, and Center.
2. Establish the prevalence of respiratory symptoms and asthma in kindergarten through sixth grade North Dakota students living in selected communities that are distant from lignite energy sources.
3. Compare the prevalence rates of respiratory symptoms, controlled for confounding factors, in the "coal country" students to the in-state comparison group. Compare the prevalence of respiratory symptoms to other published epidemiological studies.

If the study finds a statistically significant difference in the prevalence of respiratory symptoms between "coal country" and the comparison community, the EST will make recommendations of a follow-up investigation to determine factors associated with the differences. Additional research into the cause of the difference is beyond the scope of this study.

The EST, who have extensive experience in risk communication, will recommend potential methods of establishing a meaningful dialog with the community. It is the responsibility of the AP to provide community insight on appropriate methods and available communications vehicles.

3.2 Project Approach

The sponsors have chosen a cross-sectional design for this study based on recommendations of epidemiological experts. Data will be collected and analyzed consistent with other ongoing or recent air pollution health studies that offer comparison data. These include, for example, the 24-city study. The epidemiological assessment will identify and measure potential confounding factors such as indoor air quality, sex, age, tobacco smoke exposure, existing disease, and lifestyle. Comparison of the notes from

the two studied North Dakota populations will be made with control for indoor environmental factors and other potentially confounding factors.

The sponsors have selected John Spengler, Ph.D, and Jonathan Samet, M.D., as the epidemiological study team. The EST will obtain input on policy issues, health and community issues, and air quality modeling and monitoring data from the sponsors and the AP. This information will be used in the development of the study. The EST will be responsible for developing methodology for the study, preparing the project outline, project timing, hiring a project coordinator, and hiring and training staff. The EST will hire a project coordinator that will act under their direction to oversee study activities. They will also hire a data manager, quality control/quality assurance person, and research and field staff. The EST will analyze data from the field study and additional information defining potential exposures and confounding factors. The EST will work with the AP to gain additional insight as needed for interpretation of the data. They will analyze data and provide a final report.

Effective communication is critical in addressing public health issues in areas where there are conflicting beliefs. The EST will use the Advisory Panel (AP) to provide advice on the survey instruments, protocol, interpretation of results, and communication with the public, press, and sponsors. Prior to any communication with the public and press the EST will review the proposed communications with the stakeholders. The AP represents members from the medical community, public health, schools, energy and government. Sponsors have selected panel members who represent a diverse cross-section of the community.

The EST will develop a survey questionnaire with input from the sponsors, Technical Advisors Panel (TAP) and AP. This questionnaire will be used to evaluate confounding factors and prevalence of respiratory symptoms such as asthma, bronchitis, chronic cough, and wheezing and chest illness. Questions to evaluate respiratory symptoms will follow the standard American Thoracic protocol and will be modeled on health questionnaires used in other U.S. children's health studies. This instrument may need to be tested during the pilot phase of the project to train staff and evaluate clarity of questions added for this study and to assess its general suitability for use in North Dakota.

Additional testing such as pulmonary function tests may be required. The need for additional testing will be evaluated during meetings with the sponsors, TAP and AP. The decision on additional testing will be made following the pilot test of the questionnaire¹.

It is the sponsors intent to conduct the field study in the spring of 2000. Following review with the TAP and AP and approval of the stakeholders, findings will be reported to the local medical professionals and the participating communities. Methods of publicizing findings are yet to be established, but publication in the peer reviewed scientific literature is encouraged. All publications of study results will acknowledge the stakeholders and source of study funding.

3.3 Methodology

The sponsors have hired knowledgeable, competent, and experienced epidemiologists to conduct the North Dakota Children's Study. See qualifications section 6.0. A complete statistical analysis will be conducted once the field study is complete, potential confounding factors are identified, and data are interpreted. A detailed discussion of the statistical methodology can be found in Appendix A.

The questionnaire for the North Dakota Children's Health Study will not be complete in time-for grant submission, as customization is required to properly identify confounding factors. Input from the sponsors, TAP and AP will be used for questionnaire customization. A questionnaire from a previously conducted epidemiological study has been included in Appendix B for reference.

Tasks required to conduct the study are listed below:

Hire the Epidemiological Study Team (EST) – John D. Spengler, Ph.D., Professor at the Harvard School of Public Health, and Jonathan Samet, M.D., Chair of the Department of Epidemiology, Johns Hopkins School of Hygiene and Public Health, will be hired as the EST based on their experience, references, and qualifications. Both have been involved in numerous epidemiological studies.

Finalize Study Design – The sponsors and EST will finalize the study populations. School enrollment records, existing outdoor air quality data, demographics and other potential confounding

¹ At this time, the only additional testing being considered is related to verification of reported doctor diagnosed asthma.

factors will be identified prior to finalizing the study design. The AP will provide community and health perspective to the study design. The EST will customize the survey questionnaire after obtaining input from the AP, TAP and sponsors.

Selection of an Advisory Panel – The role of the Advisory Panel is to provide contextual interpretation from a community perspective. The AP includes representatives of government, the medical community, public education, energy and public health. The sponsors have jointly agreed to the makeup of the AP. See Advisory Panel biographies in Appendix C.

Selection of a Technical Advisory Panel – The Technical Advisory Panel will consist of a three-person team with expertise in asthma and/or respiratory illness and epidemiology. Makeup of the Technical Advisory Panel (TAP) will be recommended by the EST and approved by the stakeholders. The TAP will have expertise in study design and will provide advice on key study design aspects. While several individuals have been identified, selection will take place after award is made and when the EST, AP, and stakeholders confer.

Hire Project Coordinator and Field Staff – The EST will hire staff for data collection, data management, and data quality assurance/quality control. Additional staff may be hired to characterize confounding factors.

Pilot Study – The questionnaire will need to be tested following development. A pilot test of the instrument will be conducted using a convenient population. The project coordinator will interview several (10) parents on their experience completing the questionnaire. The pilot test will determine if modifications are necessary. Following the pilot test, a protocol for the study will be developed.

Field Study – Questionnaires will be distributed to the parents of kindergarten through sixth grade students through the schools. School enrollment information is included in Appendix D. The EST staff will coordinate with school departments, principals and teachers for the distribution and return of health questionnaires. The EST staff will assist in identifying and resolving anomalies in questionnaire responses. Summary data on school response rates will be presented to the EST.

Analysis Phase – Questionnaires will be optically read to create an analysis database. The database (without child modification) will undergo preliminary analysis to further identify inconsistent or contradictory responses. Protocol will determine resolution of these items leading to a final "cleaned" data set. Preliminary analysis will examine the demographics of the responding population, creating tables on the prevalence of conditions and frequency (distributions) of all variables. Target and comparison populations will be compared before applying adjustment and controlling variables to test hypothesis. Multiple logistic regression, a multivariable statistical method, will be used to examine the possible relationships among health outcomes and various measures of exposure, including 1) county/town classification, 2) ambient measured and estimated air pollution concentrations, and 3) calculated concentration at school or residence. The EST will brief the AP and sponsors as additional analysis is required and as manuscripts and reports are prepared.

Final Report – The EST will prepare a final report upon completion of the project. The final report will include a project summary, project description, project findings, supporting data, comparison statistics, background information, and any recommendations of the TAP, AP and EST. All data will be made available to the stakeholders except the original questionnaires. To protect confidentiality, questionnaires will be destroyed at the termination of the contract.

3.4 Release of Findings

All study findings will be released to the public consistent with Research studies confidential – Penalty. NDCC 23-01-15 (See page 17, Section 12.0). Stakeholder review and approval is required prior to the release of any study findings and/or reports. Methods of releasing the study findings and reports have yet to be determined.

4.0 STANDARDS OF SUCCESS

The EST has the goal of 90% response compliance with the school-based questionnaire distribution. Experience in other communities suggests that this goal can be met.

Basic standards for epidemiologic studies of this type are:

1. Adequate response rates
2. Use of survey instrument to obtain unbiased results
3. Achieving sufficient power

All three of these issues are addressed in this proposal. There will be a discussion of these issues at the first AP meeting. External technical advisors and TAP will be asked to reflect on specific aspects of design based on these relevant issues.

Sponsor acceptance of the final report of a scientifically sound and technically based epidemiological study on children's health that includes a discussion of the study goals, a project summary, project description, project findings, supporting data, comparison statistics, and background information will be deemed as successful completion of this grant. This report will provide important epidemiological data that will provide additional insight pertaining to the health of North Dakota children.

5.0 BACKGROUND

While air quality monitoring data indicate that the air quality in North Dakota meets all EPA ambient air quality standards for criteria air pollutants, the reason for conducting this study is to address concerns that all children in North Dakota do not share the same level of respiratory health. Specifically, there is a question as to whether children living in "coal country" (McLean, Mercer, and Oliver Counties), have a higher incidence of respiratory conditions than children living outside of these areas (hypothesis stated as the null). Against this local concern, there is solid national evidence that asthma has been increasing in frequency in both children and adults over the past two decades. Environmental triggers that incite asthmatic symptoms include pollens, allergens, chemicals, cold air, and tobacco smoke, among other agents. However, causative factors contributing to the incidence of new onset cases of asthma are not as well understood, although asthma, particularly in children, is considered to have a genetic basis in the majority of cases. The combined effect of genes and environment acting together, so-called interaction, is likely to be critical. To date, ambient air pollution with the criteria pollutants has not been identified as a factor leading to new asthma cases. This study examines only the possible association among the prevalence rate of current medical conditions and symptoms and various environmental, housing, and personal factors. Asthma rates derived from the North Dakota Study will be compared to those in other areas of the country to give a perspective on the North Dakota findings. Additionally, there is a growing understanding of the causes and confounding factors affecting asthma and respiratory health, which requires that such comparisons include consideration of factors such as economic status, insurance availability, exposure to second hand smoke, mold, pollen, house and agricultural dusts, house mites, allergic irritants and cold weather. In an effort to determine if there is a difference in respiratory health, the sponsors concluded that a scientifically based study was the best approach to address this question.

6.0 QUALIFICATIONS

Abbreviated curriculum vitae of the EST are found in Appendix E.

7.0 VALUE TO NORTH DAKOTA

The protection of North Dakota's citizens is an enduring commitment of the NDDH. North Dakota is one of twelve states in the nation that is in full compliance with National Ambient Air Quality Standards (NAAQS).

The lignite energy industry is the second largest industry in North Dakota accounting for 7-12 percent of North Dakota's economy depending upon which measure is used. North Dakota State University's Department of Agricultural Economics found that the lignite energy industry employed 17,384 people in 1998 - 2,914 directly and another 14,470 indirectly. In 1998, this industry accounted for \$1.3 billion in economic activity and generated \$61.6 million in state tax revenue.

All lignite facilities have been issued a Permit to Operate by the state of North Dakota. NDDH has permitted energy generating facilities in accordance with state and federal regulations to maintain North Dakota's clean air status.

Some citizens of North Dakota are concerned about increased respiratory health risks from the release of permitted pollutants within their communities. This study will provide relevant epidemiological data that will serve as a basis for evaluation of references to the health of North Dakota's children. Uncertainty about potential health effects will be resolved or possible impacts can then be considered explicitly in the ensuing strategy development.

8.0 MANAGEMENT

The study stakeholders are responsible to establish the baseline goals and objectives. Stakeholders will determine and approve the study population, approve the study design, and will be responsible for appropriation and disbursement of funding. The stakeholders will review and approve the public release of all study findings. The Lignite Energy Council is responsible for Project Management of the grant and successful completion of the project goals and objectives. Clifford R. Porter will serve as the Commission's Technical Representative and Program Manager of the North Dakota Children's Health Study Group. The EST is responsible for project coordination, study staff, analysis, and primary interpretation. Clifford R. Porter will be the primary contact for the EST. The EST will provide detailed billing for all activities to the Program Manager.

The AP and TAP provide expertise, insight and services to the study design and release of findings as detailed earlier in the proposal.

An organization chart with key personnel identified can be found in Appendix F.

9.0 TIMETABLE

A milestone chart (Appendix G) identifies key tasks and completion dates for the project.

10.0 BUDGET

The sponsors are responsible for appropriation and disbursement of all funding. The EST will submit detailed expense reports for reimbursement. Estimates for the project are shown in Appendix H.

11.0 MATCHING FUNDS

The North Dakota Children's Health Study is a joint venture. It is estimated that the study will cost \$225,000, assuming air monitoring and modeling results are available or will be the responsibility of the state and companies. Funding partners for the study are:

North Dakota Department of Health	\$75,000
<u>Lignite Energy Council – Industry Funding</u>	
Minnkota Power Cooperative	\$10,715
Minnesota Power	\$10,715
Basin Electric Power Cooperative	\$10,715
Dakota Gasification Company	\$10,715
Montana-Dakota Utilities Co.	\$10,715
Otter Tail Power Co.	\$10,715
Great River Energy	<u>\$10,715</u>
	\$75,000 ²
<u>Grant match of Industry funds</u>	
North Dakota Lignite Research, Development and Marketing Program	\$75,000

In addition to the funding listed above, the North Dakota Department of Health and the above-mentioned lignite energy industries are funding the initial study design. The initial design involves proposal preparation, data collection by the researchers and a site visit. The initial study design was approved prior to submission of this grant to the North Dakota Lignite Research, Development and Marketing Program.

² Total may not equal \$75,000 because of rounding.

12.0 CONFIDENTIAL INFORMATION

All study information is public information and full access to all data, reports, and manuscripts will be made available to the public. Only the individual's questionnaire data will be considered confidential consistent with NDCC 23-01-15. After error checking the data files, no individual identifiers will be retained. Original questionnaires will be destroyed.

N.D.C.C. § 23-01-15. Research studies confidential—Penalty

1. All information, records of interviews, written reports, statements, notes, memoranda, or other data procured by the state department of health, in connection with studies conducted by the state department of health, or carried on by the department jointly with other persons, agencies, or organizations, or procured by such other persons, agencies, or organizations, for the purpose of reducing the morbidity or mortality from any cause or condition of health is confidential and must be used solely for the purposes of medical or scientific research.
2. Such information, records, reports, statements, notes, memoranda, or other data is not admissible as evidence in any action of any kind in any court or before any other tribunal, board, agency, or person. Such information, records, reports, statements, notes, memoranda, or other data may not be exhibited nor their contents disclosed in any way, in whole or in part, by any officer or representative of the state department of health, nor by any other person, except as may be necessary for the purpose of furthering the research project to which they relate. No person participating in such research project may disclose, in any manner, the information so obtained except in strict conformity with such research project. No officer or employee of said department may interview any patient named in any such report, nor a relative of any such patient, unless the consent of the attending physician and surgeon is first obtained.
3. The furnishing of such information to the state department of health or its authorized representative, or to any other cooperating agency in such research project, does not subject any person, hospital, sanitarium, rest home, nursing home, or other person or agency furnishing such information, to any action for damages or other relief.

Amended by L. 1995, c.243, § 2, eff. Aug. 1, 1995.

13.0 TAX LIABILITY

I, John Dwyer, certify that the Lignite Energy Council is not delinquent on any tax liability owed to the State of North Dakota.

John Dwyer, President
Lignite Energy Council