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Dr. Richard W. Perkins
Battelle
Pacific Northwest Laboratory
P. O. Box 999
Richland, Washington 99352

Dear Dr. Perkins:

A preliminary review of your Schedule 189 submission entitled "Aerosol Deposition in Human Lungs from Energy Sources and Urban Pollution" has been completed by BER staff members. Dr. Maletskos also discussed the proposal with Dr. Carter, Dr. Marks, Mr. Beadle and myself on November 11, 1975. As there is a clear recognition of the need for studies of the type you propose, there is agreement that your proposal deserves further consideration for funding. However, before any final decision is made, we consider it necessary to submit the proposal to a group of outside reviewers for further review. In this regard we question if the proposal, as it is now written, provides sufficient detail for reviewers to adequately comment on certain aspects of the proposal. With this in mind we would appreciate your preparing supplemental material for the proposal. This could be in the form of a supplement to the 189 submission. The following are the areas in which we feel more detailed information is needed prior to further review. Two very broad questions that should be addressed are:

1. Has the biostatistical input into the proposal been adequate to insure its feasibility and practicality, and will the necessary biostatistical support be available during the project? We feel that a well qualified individual or individuals should be included as co-investigators.
2. Is the experimental design adequate to accomplish the objectives of the proposal? In this regard more detail or references on the experimental methods to be used should be provided so that reviewers may judge their adequacy. Are the pathologists willing to cooperate in using the special techniques necessary for sample collection and analysis?

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A number of more specific questions have been raised relating to the above questions. These are included as examples of the types of issues that should be addressed.

1. How will the locations for the 10 aerosol sampling stations be selected? Will the data being collected on St. Louis air quality by such programs as RAPS be considered when the locations are selected? Will every effort be made to utilize data from other studies in St. Louis to maximize the types of correlations that maybe possible?
2. What is the basis for the selection of 20 individuals per subgroup for analysis? Is this sample size sufficient? Can the data on St. Louis deaths be examined prospectively to insure that the mortality pattern will support the study?
3. With what is now known about the distribution of trace elements in aerosols, both in regard to aerosol size distribution and variation from location of collection, and what is known about the trace elements in human tissues, is it reasonable to expect that the types of correlations proposed will be observed in the samples selected for analysis?
4. With what is known about the chemical form of aerosols in St. Louis is there a reasonable chance that the modeling effort will be successful in separating the inhaled from the ingested burden of the materials in question?
5. Will the tissue sampling procedures be adequate? For example will the pathologists be willing to consistently sample a certain area of lung for analysis? Considerations of this type are necessary due to the known nonhomogeneous nature of distribution of material within the lung. Are the samples proposed consistent with what is known about the distribution of trace elements within the body? For example, shouldn't bone be included as a sample?
6. What criteria will be used for inclusion of the tissues of an individual in the study (i.e., work history, time in area)?

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- 7. Would it be feasible to monitor for other pollutants such as SO₂ and polycyclic organic materials at these same aerosol sampling locations? What would the additional cost be? It is recognized that it is not feasible to correlate the data on these materials from the aerosols with levels in the tissues.

We appreciate that revisions of this type will require considerable effort on your part. However, with only limited funding available we must insure that any available funds are allocated to the highest quality proposals. It is also essential that you recognize it is uncertain when funding for a proposal of this magnitude would become available even if favorable reviews are received. Hopefully this situation will be resolved over the next few months, but at the present it appears unlikely that full funding would be available prior to FY 77.

Sincerely,

Charles H. Hobbs, D.V.M.
Biomedical Programs
Division of Biomedical and
Environmental Research

cc: Dr. Marks
Mr. Beadle

OFFICE →	BP	BP				
SURNAME →	CHHobbs:gas	Carter				
DATE →	11/25/75	11/11/75				

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