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PROCEEDINGS OF THE NHEXAS DATA ANALYSIS WORKSHOP

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NHEXAS ANALYSIS WORKSHOP
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1. INTRODUCTION

The National Human Exposure Assessment Survey (NHEXAS) was developed by the Office of Research and Development (ORD) of the U.S. Environmental Protection Agency (EPA) early in the 1990s to provide critical information about multipathway, multimedia population exposure distribution to chemical classes. The first phase consisted of three pilot studies with the objectives of (1) evaluating the feasibility of NHEXAS concepts, methods, and approaches for the conduct of future population-based exposure studies; (2) evaluating the utility of NHEXAS data for improved risk assessment and management decisions; (3) testing the hypothesis that the distributions of exposure given by modeling and extant data do not differ from the measurement-based distributions of exposure; (4) defining the distribution of multipathway human exposures for a relatively large geographic area; and (5) stimulating exposure research and forging strong working relationships between government and nongovernment scientists. NHEXAS began before the enactment of the Government Performance and Results Act (GPRA), which was written to ensure accountability in the use of resources. Thus, we add a "new" objective in the form of a hypothesis: NHEXAS approaches can be used to develop a "GPRA Report Card" on the efficacy of EPA's regulations to reduce exposure.

As described in the overview (Section 2), NHEXAS is a unique and complex study of approximately 550 people in three areas of the United States. The data collection phase of NHEXAS was completed recently, the initial data analyses will be published shortly (see October issue of the Journal of Exposure Analysis and Environmental Epidemiology (JEAEE), Appendix 1), and the principal investigators have additional analyses under way (Appendix 1). During a September 1998 review, the Integrated Human Exposure Committee (IHEC) of EPA's Science Advisory Board (SAB) (U.S. EPA, 1999) praised the NHEXAS pilots and recommended several actions to ensure that as much benefit as possible is derived from this very rich database. One such action was to develop a strategy for completing the analysis of the NHEXAS pilot data. To those ends, a workshop was convened with the goal of obtaining a wide range of expert opinion on which research projects best would ensure the utility of the NHEXAS data. Section 3 provides an overview of the workshop, and as described therein, the workshop projects will be used as information in developing the ORD strategy for analysis of the NHEXAS pilot data.

The workshop was successful in developing and suggesting a relative priority for research projects that covered the range of potential data analyses, including those that will support future exposure assessments, advance the science of exposure analysis, demonstrate lessons learned, and become part of the development of multimedia, multipathway exposure models. The project descriptions, categorized within the four research areas, are provided in Section 4.

Supplementary information is provided in the appendixes.

2. OVERVIEW OF NHEXAS

2.1 BACKGROUND ON EXPOSURE TO CHEMICAL POLLUTANTS

To assess the risks posed by chemical pollutants in the environment, EPA must be able to estimate the number of people exposed to these chemicals and the intensity of exposure. In the past, most studies have focused on exposure to one chemical at a time by one route of exposure. For instance, a study might look at how much of a particular chemical is found in outdoor air. In many cases, these studies have relied on very indirect measures to estimate exposure to the chemicals. An example would be to sample emissions from a smokestack and then apply air transport models to predict exposure to residents in the surrounding area.

Although such studies are important, looking at chemicals and sources in isolation does not reflect actual patterns (distributions) of human exposure to chemicals in the environment. In reality, people can be exposed to chemicals from a variety of sources that contaminate water, food, air, dust, and other media. Exposure to a single chemical may occur from contact with several environmental media (e.g., air, water), via several pathways (e.g., hand-to-mouth transfers, food), and through several routes (i.e., inhalation, oral, dermal). Additional complexities arise when considering an individual's exposure to multiple chemicals at any point in time or over extended periods. The fact that different people also spend varying amounts of time indoors and outdoors or otherwise engage in activities that can have important impacts on chemical exposure adds to this complexity. More accurate assessments of risks, therefore, must take into account exposure to multiple chemicals from various routes and media.

By understanding total or aggregate exposure, it also will be possible to identify those pathways and routes responsible for the greatest exposure, thereby providing direction for decisions on the most effective strategies to reduce risks.

2.2 THE PURPOSE OF NHEXAS

NHEXAS in its fullest sense is a conceptual design, which, on implementation, will have long-term implications to exposure research and assessment. The ultimate goal is to document status and trends of national distributions of human exposure to potentially high-risk chemicals to improve the accuracy of exposure (and risk) assessments and to evaluate whether exposure (risk) is deteriorating or improving over time with the application of risk management steps. However, such an extensive program requires much preparation, including making improvements in the state of exposure science. The Phase I pilot projects, which are the topic of the workshop, are the beginning. Based on the scientific advances from this first phase of NHEXAS, two follow-up phases are envisioned. One encompasses special studies to test particular hypotheses related to issues, such as characterization of a pathway of concern for a specific subpopulation or a chemical of concern at specific geographic scales (community and regional) or an uncertainty related to the effect of temporal variability in an exposure assessment model. The second is the design and implementation of a much broader national survey of population-based exposures building on the foundation laid by the pilot-phase investigations.

Phase I of NHEXAS (hereafter referred to as just NHEXAS or pilot NHEXAS studies) is perhaps the most ambitious study ever undertaken to evaluate *total* human exposure to multiple chemicals on both community and regional scales. It focuses on the exposure of people during their daily lives to environmental pollutants. To accomplish this, hundreds of volunteer participants were selected randomly from several areas of the country to obtain a population-based probability sample. NHEXAS scientists measured the levels of a suite of chemicals to which participants were exposed in the air they breathe, in the foods and beverages they consume, in the water they drink, and in the soil and dust around their homes. Measurements also were made of chemicals or their metabolites in biological samples (including blood and urine) provided by the participants. Finally, participants completed questionnaires to help identify possible sources of exposure to chemicals and to characterize major activity patterns and conditions of the home environment.

In addition to improving estimates of total exposure to chemicals, NHEXAS has the following aims.

- Identify subgroups of the general population that are likely to be highly exposed (at least the 75th percentile) to chemicals in their environment.
- Provide a baseline of the normal range of exposure to chemicals in the general population that can be used to compare to the results of other investigations conducted at particular sites of concern or addressing specific routes.
- Compare the results of a one-week "snapshot" of exposure to the results obtained from multiple sampling cycles over a year.
- Evaluate and improve the accuracy of models developed to predict or diagnose exposure of people to chemicals.
- Test and evaluate different techniques and design approaches for performing multimedia, multipathway human exposure studies.

2.3 HISTORY AND PARTICIPATING ORGANIZATIONS

Currently, NHEXAS consists of three interrelated projects, all of which were funded as cooperative agreements and coordinated by EPA's Office of Research and Development:

(1) a study of several hundred Arizona residents by the University of Arizona, Battelle Memorial Institute, and the Illinois Institute of Technology;

(2) a study of several hundred residents from the states of Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin by the Research Triangle Institute and the Environmental Occupational Health Sciences Institute, and, also, a smaller scale study focused on children's exposures to pesticides, conducted with the participation of the Minnesota Department of Health; and

(3) a study of about 60 Maryland residents by Harvard University, Emory University, Johns Hopkins University, Southwest Research Institute, and Westat.

Two other federal agencies, the Food and Drug Administration and the Centers for Disease Control and Prevention (CDC), assisted EPA (under interagency agreements) with sample analysis. The National Institute for Standards and Technology (NIST) under an interagency agreement, provided quality assurance (QA) support.

Within EPA's ORD, scientists from the National Exposure Research Laboratory (NERL), National Center for Environmental Assessment (NCEA), and the National Health and Environmental Effects Research Laboratory (NHEERL) participated. The first two organizations are engaged actively in the conduct of the program by serving as project officers and principal collaborators in the research.

Sample collection began in mid-1995 and was completed for all of the projects in late 1997, and the planned analysis of the samples was completed in early 1998. Publications are beginning. Actual databases are expected to become available to the public in 2001.

2.4 MAJOR DESIGN ELEMENTS

Table 1 summarizes the major design elements of NHEXAS. There were common features across the three consortia. All three consortia used the same basic set of questionnaires. Within chemical classes selected by the consortia, each consortium analyzed for a basic set of chemicals (primary analytes). However, by utilizing three consortia, alternative and innovative variations on the theme of multimedia measurements to estimate total human exposure were possible. For example, each consortium was able to target some specific concerns or opportunities. Two of the consortia focused on measuring potential exposures of each participant once; one consortia studied fewer people but repeated the measurements several times over the year to enable estimates of temporal variability for the exposures and activities of interest.

The participants were selected through a probability sample to permit statistical inferences about the larger population later. The only exception was a special panel on children exposed to pesticides. (This was based on oversampling households reporting more frequent applications of insecticides and on a commercial listing of households with listed telephone numbers that were predicted to have age-eligible children.)

Chemicals to be analyzed by NHEXAS were chosen because they are known (or strongly suspected) to present major environmental health risks, had been found in two or more environmental media (air, water, soil, or food), and had been identified as being of importance to several EPA program or regional offices or to other federal agencies. Chemicals were selected only if it was feasible to collect and analyze them. The chemicals fall into three categories:

TABLE 1. SUMMARY OF NHEXAS STUDIES

	Consortium		
	University of Arizona/Battelle Memorial Institute/Illinois Institute of Technology	Research Triangle Institute/Environmental and Occupational Health Sciences Institute	Harvard/Emory/Johns Hopkins/ Southwest Research Institute/Westat
Type of Study	Exposure field study	Exposure field study Data analysis and hypothesis testing (CAG-PIs and ORD-PCs [a]); database integration (NERL and NCEA)	Special study: relation of short-term data to longer term exposures
Geographic Region	Arizona	Region V (Illinois, Ohio, Indiana, Michigan, Minnesota, and Wisconsin)	Baltimore and surrounding counties
Design	Representative sample of general population	Representative sample of general population	Representative sample includes suburban, urban, and rural groups
Approximate Number of People	179 (plus others in sampled households)	249 (plus 52 for pesticides) (no others in sampled households)	53 people sampled six times over 1 year
Analytes	Pb, As, Cd, Cr, Ni, Ba, Mn, Se, V, Cu, Zn; benzene, chloroform, perchloroethylene, trichloroethylene, methylchloroform, styrene, toluene, xylene, *p*-dichlorobenzene, formaldehyde, 1,3,-butadiene, methylene chloride, carbon tetrachloride, plus 11 additional volatile organic compounds (VOCs); chlorpyrifos, diazinon, malathion, carbaryl	Pb, As, Cd, Cr; benzene, chloroform, perchloroethylene, trichloroethylene, methylchloroform, styrene, toluene, xylene, *p*-dichlorobenzene; chlorpyrifos, diazinon, malathion, atrazine, chlordane, dieldrin, heptachlor, 4,4'-DDE, -DDD, and -DDT; B(a)P, anthracene, phenanthrene, pyrene, B(a)A, acenaphthylene, fluoranthene, B(g,h,i)perylene, indeno(1,2,3-c,d)pyrene Children's Study (pesticides and PAHs)	Pb, As, Cd, Cr; chlorpyrifos, diazinon, malathion, atrazine (water only), chlordane, dieldrin, heptachlor, 4,4'-DDE, -DDD, and -DDT; B(a)P, anthracene, phenanthracene, chrysene
Samples	Air, water, food, and beverages; soil/dust and surfaces; urine and blood	Air, water, food, and beverages; soil/dust and surfaces; urine and blood	Air, water, food, and beverages; soil/dust and surfaces; dermal; urine and blood
Questionnaire	NHEXAS	NHEXAS	NHEXAS

[a]CAG-PIs = principal investigators of cooperative agreements; ORD-PCS = principal collaborators from ORD.

(1) volatile organic compounds (VOCs), such as trichloroethylene, benzene, and perchloroethylene; (2) metals, such as lead, arsenic, and cadmium.; and (3) pesticides, such as the herbicide atrazine and the insecticides chlorpyrifos, diazinon, and malathion. In some media, measurements of selected polycyclic aromatic hydrocarbons (PAHs) were made.

2.5 SOURCES OF MORE INFORMATION

A special issue of JEAEE (vol. 5, no. 3, July-Sept., 1995) describes all major aspects of NHEXAS in detail. At present, several manuscripts have been submitted to JEAEE and will be published in October 1999. Appendix 1 lists the papers in preparation and in press.

3. OVERVIEW OF THE WORKSHOP

On September 28 and 29,1998, EPA's SAB IHEC reviewed the NHEXAS pilot studies and provided an advisory to EPA. Their major findings are shown below.

- NHEXAS pilots are scientifically "outstanding in both design and implementation...."
- The NHEXAS design "can help to identify serious human health risks, to decide what interventions would be helpful in reducing these risks, and to document the effectiveness of interventions in actually reducing exposures."
- The "NHEXAS pilot study is highly relevant to the Government Performance and Results Act (GPRA) and SAB's "integrated Environmental Decision-Making Framework," which emphasize performance evaluation as a key to effective environmental health protection."
- ORD should develop a feasibility study for a national-scale human exposure survey.
- ORD should publicize the significance of NHEXAS framework and continue to build partnerships.
- ORD should provide additional resources to strengthen analysis of NHEXAS pilot data or the "expenditures incurred during the last five years would be of limited utility."
- "The EPA should conduct a cost-benefit analysis of the various components of the study."
- A database of the NHEXAS information (with appropriate QA) should be developed and made widely available.

- ORD should develop a strategy for the analyses of the NHEXAS data, and the SAB should review it.

ORD is in the process of following-up on all these recommendations. It was decided that a workshop format would be used to begin the development of an analysis strategy. Appendix 2 shows the workshop agenda. Input was sought from individuals with a wide range of expertise so that perspectives from practitioners of the science as well as users of the science would be represented; from NHEXAS investigators and their peers; from measurement and modeling experts; and from federal and non-federal experts (Appendix 4). The goal was to define potential analysis projects (with priority rankings) as the centerpiece of a proceedings. Then this proceedings would become input into ORD's development of a draft analysis strategy, with priorities. This draft will be made public at the time of submission to the SAB (approximately November 1999, assuming that the SAB review will be in December 1999; however, the date has not been set). After SAB review, ORD will revise the strategy and use it as a guide to research planning. Research will be implemented, consistent with resources available, by in-house tasks, contracts, or assistance agreements (cooperative agreements and grants), as appropriate according to procurement regulations and laws.

Workshop participants were divided into four breakout groups (see Appendix 3) to enable extensive interchange of ideas. Each group had a mixture of expertise to raise provocative ideas. For example, participants were from academia, independent research institutes, EPA program offices, all ORD laboratories and centers, the National Institute of Environmental Health Sciences (NIEHS), Centers for Disease Control and Prevention, the American Petroleum Institute, and the departments of health of Minnesota and New York. The groups focused on the areas described below.

- **Assessment.** This covers analyses that would result in descriptive statistics for questionnaire and measurement data, comparisons among the NHEXAS and other studies, total exposure estimates, cumulative exposure assessments, identification of relative contributions of pathways to exposure, etc.
- **Exposure Analysis.** This covers analyses that would study design hypotheses (plus those proposed at this workshop), characterize temporal variability, identify factors that contribute to a high-end exposure, characterize urban-rural differences, and describe relationships among various components in the human exposure process (including sources, concentrations, exposures, human activities, and dose).

- **Lessons Learned.** This covers analyses that inform everyone about study elements that will be generally useful in the future or that will require modification or deletion in follow-up research. This includes descriptions of the achievement of data quality objectives and of response rates and survey design effects; evaluation of the ability of questionnaire environmental and biological data to predict exposure and dose; a comparison of sampling and analytical methods; the efficacy of communication with states, local public health departments, communities; etc.
- **Exposure Modeling.** This covers the application of NHEXAS data to the development or refinement of multimedia, multipathway exposure models and the evaluation of the reliability of existing models. This includes applications to other agency models such as the Total Risk Integrated Methodology (TRIM), Cumulative Exposure Model (CEM), etc., and use in predicting exposures from biomarker concentration and in predicting biomarker concentrations from exposure and environmental concentration levels and in characterizing pathways; etc.

The workgroups were charged with identifying, writing, and prioritizing potential analysis projects. Before the workshop they received some background material (Appendix 6), as well as a list of the SAB recommendations for analyses and key analyses questions to drive the discussion (see Sections 4.2.1 through 4.2.3, 4.3.1 through 4.3.3, 4.4.1 through 4.4.3, and 4.5.1 through 4.5.3). Within each group, the participants discussed these and other related issues, developing a preliminary list of a large number of projects. This list was then prioritized, with the goal of selecting 10 to 15 high-priority projects to be expanded according to a preestablished format. Project description formats were developed that would be informative enough for strategic planning, without being so detailed as to contain intellectual property or to provoke the need for recusals in later resource competitions. Members of the workgroup were assigned to draft the project descriptions, which then were discussed by the whole group. The group then created the prioritized list, typically by applying multivoting techniques. The preliminary lists and the ranked project descriptions are provided in Section 4.

The workgroups reported in plenary session on the last morning. Limited discussion followed to ensure the project descriptions covered all the NHEXAS objectives and major points.

The workgroup chairs and rapporteurs and others on the organizing committee continued to work to improve the clarity of the project descriptions, without changing their substance and to create the proceedings, which are provided in Section 4. The handouts provided either at or prior to the workshop, as well as the overheads from the overview presentations on the first day, are provided in Appendixes 5 and 6, respectively.

4. PROJECT DESCRIPTIONS

4.1 INTRODUCTION

Edited versions of the project descriptions developed at the workshop are presented according to their workgroup. They all have the same format. The project name is preceded by a code that consists of an abbreviation of the group name (e.g., LL for lessons learned) and the priority assigned by the workgroup. Pertinent information is provided (i.e., description, goal, significance, approach). The entry on data or input needs is valuable to identify pacing items; for example, a data or input need may be a high-quality database or summary statistics, indicating what work would need to be done first. Also, the section on feasibility can be quite important. For example, some analyses will require a certain level of data completeness. Most of these types of details were not available at the workshop, making it necessary to identify them on the descriptions. The participants also identified research outputs and timelines, as well as an approximate level of effort. This is important because the level of effort and timeline are mutually dependent and can be interpreted as broad resource needs.

Each subsection to follow begins with a list of the SAB recommendations, questions to the participants, and discussion considerations that provided guidance to the workgroups. As mentioned, all the groups began with brainstorming and then sorted out the highest priorities for development of project descriptions. The modeling group had similar projects before and after this procedure. The early brainstorming lists for the other three groups are provided below. The last portion of each subsection contains the project descriptions, in priority order. It must be emphasized that there are minimal differences in priorities within groups. Basically, the priorities represent minor variations on a class of high-priority projects with the exceptions noted in the Assessment Group. The criterion for priority was very broad (value to science), and the participants (each with one vote) represented a wide array of interests and perceptions. Therefore, the primary value of the prioritization is that it ensured that only the highest priorities would emerge, rather than to compare the value of a project of rank 3 versus rank 6.

As mentioned, each workgroup has a subsection. There was no time available (nor an attempt) to prioritize among the groups because of the desire to focus effort on identifying analysis needs rather than polishing suggestions. The reader will notice some actual and apparent overlaps across the groups. Useful merging will be accomplished in the ensuing ORD strategy. The reader also will see that there are inputs (e.g., databases, questionnaire results) common to many projects.

4.2 ASSESSMENT GROUP

The assessment breakout group will focus on analyses that will result in descriptive statistics for questionnaire and measurement data, comparisons among the NHEXAS and other studies, aggregate exposure estimates, cumulative risk estimates, and identification of relative contributions of pathways to exposure.

4.2.1 SAB Comments

In their review of the NHEXAS pilot projects, the SAB made several comments regarding the use of NHEXAS data in exposure assessment; these are presented below.

(1) Key elements of the strategic plan for data analysis should include...critical evaluation of the potential value of meta-analysis across the three subcomponents of NHEXAS, development of a plan for any meta-analysis, and, finally, the identification of findings of considerable importance to help EPA in some current risk management efforts (the early analysis of the NHEXAS data suggest that there may be findings of this nature) [3.2.2.a, items 6 and 7][1]

(2) Once descriptive and summary statistics have been completed, concentration data should be transformed into exposure data.... Further work needs to be done to integrate total exposures from all media and to estimate long-term exposures from short-term measurements. [3.2.2.d]

(3) In the near term, prototypical analyses of exposure and assessments of intervention strategies should be made for a variety of chemicals measured in the NHEXAS pilot program. [3.3.1.a]

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[1]Numbers in brackets are cross-references to section in the SAB report.

(4) The IHEC recommends the following to improve the quality and utility of the databases from the three pilot studies [3.3.1.b]:

- the databases from Arizona and Region V should be integrated in some fashion;
- the NHEXAS researchers should assess the implications of the Maryland study for the Arizona and Region V studies;
- the NHEXAS results should be integrated with information on criteria pollutants from fixed site monitoring stations; and
- the databases from NHEXAS and the National Health and Nutrition Examination Survey (NHANES) should be cross-referenced in a fashion that fully takes advantage of the complementarity of the data.

(5) The EPA should use the NHEXAS data to assess source-to-dose trends for chemicals such as lead, benzene, and PAHs. [3.5.1.e]

4.2.2 Questions To Address

As a starting point to identify, describe, and prioritize potential projects, the breakout group should consider the following questions and determine what additional critical questions should be added.

(1) What exposure assessments should be done using combined data from two or more NHEXAS studies or combining data from NHEXAS with data from other studies? What comparisons of results should be made between the NHEXAS studies and other studies, such as the Total Exposure Assessment Methodology (TEAM) Study and NHANES?

(2) What chemical-specific exposure assessments, identified by target chemicals and routes and pathways of exposure, should be done? What multipathway assessments should be done?

(3) What exposure assessments should be done for subpopulations represented in the NHEXAS study?

(4) What multichemical cumulative risk assessments within chemical classes should be done?

(5) What risk assessments should be done comparing risks across chemicals or chemical classes?

(6) What exposure and cumulative risk assessments should be done to examine trends in exposure concentrations, estimated doses, body burden, and source contributions to dose?

(7) What analysis of NHEXAS data should be done to provide distributions of exposure factors for use in assessments?

(8) What, if any, exposure assessments of intervention strategies should be done comparing NHEXAS data with existing preintervention data.

(9) What exposure and risk assessments should be done to help prioritize EPA program activities?

4.2.3 Discussion Considerations

(1) What are the appropriate methods for combining NHEXAS data for different exposure pathways and exposure routes? Consider methods such as exposure models, probabilistic assessment, and physiologically based pharmacokinetic models.

(2) How should the high end of distributions such as an exposure concentration or an intake (above about the 90th percentile) be treated, given that, at best, the samples are large enough to estimate the 90th percentile? Can this limitation be overcome by combining data sets?

(3) Are the data for a particular chemical sufficient to support a given exposure or risk assessment? If the data are not sufficient, what other data are available to fill data gaps?

(4) How should NHEXAS data across the consortia be treated in an exposure assessment of a common target chemical, such as lead? Should data sets be combined or treated separately?

(5) How does one conduct a multichemical assessment? How are the outcomes of the assessment put on a common basis so that they can be combined and compared?

(6) How are biological data used in exposure and risk assessments?

(7) How should temporal variability be treated in exposure and risk assessment? What is the appropriate exposure duration over which exposure can be assessed? How can NHEXAS data be used to assess acute, subchronic, and chronic exposures, and what are its limitations?

(8) How can uncertainty and variability in exposure and risk assessments be characterized using NHEXAS data?

4.2.4 Brainstorming List of Projects

The following is an unranked list of 29 assessment projects proposed by the Assessment Break-Out Group on July 27, 1999. On July 28, the group combined this list into 13 projects for development; no areas were eliminated from consideration. The numbers in parenthesis following the titles are cross-references to the projects in Section 4.2.5.

1. Investigate the use of food frequency data to complement such surveys as the U.S. Department of Agriculture (USDA) food consumption surveys. (A10)
2. Compare exposure assessments from the duplicate diet study with assessments based on the traditional diary/recall data and residue databases. (A10)
3. Develop population distributions from NHEXAS data. Include distributions to the total population and for selected subgroups. (A2)
4. Compare NHEXAS biomarker information to similar information from other studies (e.g., NHANES). (A2)
5. Look at correlation between blood levels and air levels of contaminants from Arizona and Region V studies. (A5)
6. Use NHEXAS to assess risks, compare risks, and set priorities. Determine the contribution of specific sources, pathways, and routes to risks (e.g., lead versus organophosphates). (A6a)
7. Comparison of questionnaire data to biological data. Use for factor analysis to determine the most important determinants of exposure. (A5)
8. Use of questionnaire data to screen for highly exposed subgroups. (A11)
9. Use diary and time/activity data to assess the association between exposure and repeated versus infrequent activities. (A6b)
10. Where complete data for an individual exists, correlate activities with exposure (look at space and time). (A6b)
11. Does integrated personal inhalation exposure correlate with area compliance monitoring? (A9)
12. Determine the relationship between indoor and outdoor exposure. Develop a distribution of ratios of indoor to outdoor. Compare ratios to other studies. (A9)
13. Determine if there is a good tracer chemical for tracking ambient to indoor exposure. (A11)
14. Determine highly exposed groups for specific and multiple chemicals. (A5)

15. Can exposure factors from NHEXAS questionnaires be generalized (e.g., incorporated into the Exposure Factors Handbook)? Look at distributions and point estimates. (A2)
16. Identify behaviors associated with high exposures. (A5)
17. Correlation analysis between activity/climate and water intake. (A6b)
18. Compare Minnesota children to adults in Arizona and Maryland. Are children more highly exposed to metals and VOCs in Minnesota? (A8)
19. Correlation of mercury in hair and fish consumption, air levels, etc. (A3)
20. Correlation between biomarkers and environmental samples—identify important media, pathways, etc. (A3)
21. Preemptive list of caveats, limitations, etc. Uncertainties. (A2)
22. Can NHEXAS data be used to develop behavior scripts (scenarios)? (A6b)
23. Comparison of methods among the three components of NHEXAS. (A11)
24. Compare a cumulative exposure (as measured by biological samples) to co-occurrence in media. (A1, A3, A6a)
25. Temporal comparisons, geographic comparison, relationship to sources (indoor and outdoor). (A4, A12)
26. Appropriate averaging time—extrapolations using Maryland study to build a temporal model and extrapolation model. (A4)
27. Temporal variability in total exposure. (A4)
28. Temporal comparisons with attention to interventions implemented before NHEXAS. (A13)
29. Comparison of questionnaire results to past studies such as TEAM to see if there are trends in activity (e.g., what is causing increases in asthma?). (A13)

4.2.5 Project Descriptions

[Note: Projects identified with "a" or "b" are tied for ranking (e.g., A6a and A6b), and the top five projects are clearly of higher priority than the last three projects.]

Project Name:	**A-1. Analysis of the Joint Distributions (Co-occurrence) of Chemical Exposures**
Short Project Description:	Using data on individual chemical species in personal air, dust, dietary, and biological samples (each analyzed separately), use multivariate statistical methods to determine whether concentrations co-vary across subjects for different chemicals or not. If not, identify groups of chemicals that vary together across the population and/or that cluster together in upper percentiles of exposures (e.g., upper 10th, upper 25th, depending on availability of data), and analyze the ability of questionnaire-based variables to predict whether a person falls in the upper tail of the joint distribution.
Goal/Objective:	(1) Where feasible, combine data on individual chemical species across the three NHEXAS sites for personal air, dust, dietary, and biological samples. (2) Test whether the distributions of individual chemical exposures correlate with one another across the pooled population. (3) Using factor analysis and discrete multivariate methods (for measurements and strata, respectively), identify groups of chemicals that vary jointly. (4) Analyze whether there are questionnaire-based variables that can predict high-end, joint multichemical exposures.
Significance of Project:	A key question in assessing risks of environmental exposures is whether distributions across people in exposures to chemicals A, B, C, ... are independent of one another, or whether, instead, the distributions are correlated? That is, are there individuals who fall in the upper tails of more than one chemical exposure distribution, or, put another way, are there groups of chemicals that tend to rise and fall together across the population? If so, this would have important implications for risk assessments addressing cumulative exposures.
Suggested Approach:	(1) Using pooled data (if possible) across NHEXAS studies, construct bivariate correlation matrices for all chemicals analyzed. Construct separate tables for personal air, dust, diet, blood, and urine data. (2) Carry out factor analyses to identify groups of chemicals that vary together across the population. (3) Dichotomize exposure distributions into $90th percentile or not. Analyze whether assignments are correlated across chemicals. (4) Characterize the chemical groupings, if any, and use regression analysis to identify predictors of high joint exposures.
Data or Input Needs:	Chemical-specific concentrations measured in personal air, dust, diet, blood, and urine samples from the three NHEXAS pilots.
Feasibility (of analyses with current NHEXAS databases):	High feasibility. This analysis exploits the rich data on multiple chemical exposures provided in the NHEXAS database. Each consortium will be developing summary statistics for its data, which will be used in this project.

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0-6	(1) Initiate project: Assemble, combine, check data from three sites
	Month	9	(2) Initial descriptive analyses including bivariate correlations
	Month	18	(3) Complete multivariate analyses
	Month	24	(4) Final outputs: Report and publish

Approximate Level of Effort:	% Time	Months	Type of Expertise Needed
	10-20	24	Principal investigator (exposure assessment/biostatistics)
	100	24	Post-doc or doctoral student trained in exposure assessment and biostatistics

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: Many scientific issues must be dealt with (e.g., things may be correlated, but is there a causal relationship?), and issues related to different sampling protocols may arise.

Project Name:	**A-2. Univariate Statistics for Use in Exposure and Risk Assessment**
Short Project Description:	Develop univariate descriptive statistics (distributional information) for NHEXAS data that can be used broadly in exposure and risk assessment.
Goal/Objective:	To provide risk assessors and other users with information for use in exposure and risk assessment and in the design of human health effects studies and to compare NHEXAS results to other existing relevant study results.
Significance of Project:	Exposure and risk assessors use estimates of various exposure concentrations and "exposure factors" in their calculations of exposure and risk. These are quite often point estimates or distributions from very limited data sets. The data collected by NHEXAS can be used to better define distributions of these concentrations and exposure factors (e.g., activities, time spent in specific locations, dietary intake, product use). This will reduce the uncertainty associated with these assessments. Major users of this information will be risk assessors in EPA, other federal agencies, industry, academia, and state and local governments, as well as epidemiologists and other health effects researchers who need to classify members of a cohort based on exposure.
Suggested Approach:	Work with EPA/NCEA to identify factors and point estimates that commonly are used in risk assessment and for which data were collected in one or more of the NHEXAS pilots. Develop summary statistics (including distributional information) for these data. These analyses should include distributions for the total population and for selected subgroups where the data will allow. These should be suitable for inclusion in EPA guidance, such as the Exposure Factors Handbook. These analyses should identify the appropriate caveats, limitations, and uncertainties associated with the data and resulting statistics. The results should also compare the statistics with similar information from other studies (e.g., NHANES, TEAM).
Data or Input Needs:	The activity and concentration data collected by all NHEXAS pilot studies. Summary descriptive statistics. Meta-data to understand caveats. Other data sets (e.g., NHANES, TEAM, Exposure Factors Handbook).
Feasibility (of analyses with current NHEXAS databases):	This is highly feasible with NHEXAS data. Each consortium will be developing summary statistics for its data. It should be feasible to identify factors for inclusion in EPA guidance.

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project
	Month	6	(2) Scoping description and project plan
	Month	12	(3) Provide statistics to EPA, including descriptions of the data and its limitations for use in risk assessment
	Month	24	(4) Revision of Exposure Factors Handbook
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	5	24	Principal investigator
	10	24	Senior-level staff ("associate")
	100	24	Junior-level staff ("assistant", technician), students
	100	24	Senior statistician

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: Significant ORD involvement will be needed on this project.

Project Name:	**A-3. Aggregate Assessment**
Short Project Description:	This project will estimate aggregated exposures from all media and all pathways for a single chemical using environmental concentrations and biological testing results.
Goal/Objective:	(1) Identify the important media, pathway, and routes that contribute the most to total exposure; (2) Identify or develop methodologies (or models) to analyze the relationships between biological testing results (i.e., blood and urine samples), environmental and personal concentrations, and exposure/dose. (3) Investigate correlation between exposure (dose) via single pathways and total exposure (dose).
Significance of Project:	(1) Address the important regulatory issues associated with single- and multimedia exposures (e.g., air, water, and contaminated soil or food). (2) Advance the exposure assessment methodology (multimedia and multipathways). (3) Help EPA to prioritize resources to address the most important media or pathways and to design intervention strategies to protect public health.
Suggested Approach:	(1) Look at correlation between biomarkers (blood and urine concentrations) and environmental concentrations (e.g., correlation between blood levels and air levels of contaminants from Arizona and Region V studies—indoor, outdoor, personal (e.g., correlation of blood lead and concentrations in house dust and soil). (2) Identify or develop an aggregate model structure to assess the exposure for an individual (multimedia, multipathways). The Department of Energy has developed several multimedia exposure models for its dose reconstruction projects. It is suggested that those models be reviewed for this project's use. (3) Identify exposure factors from questionnaires (e.g., intake rates). (4) Calibrate models using NHEXAS data; therefore, the models can be used in the future. (5) Evaluate uncertainties and limitations associated with methodologies, data, and models.

Data or Input Needs:	(1) Environmental concentration data in all media. (2) Total biological testing data. (3) Exposure pathways and routes associated with each media. (4) Coefficients (e.g., uptake rates, absorption rates).
Feasibility (of analyses with current NHEXAS databases):	(1) Adequate environmental concentration data. (2) Biological testing results. (3) Knowledge about correlation between media concentrations and biological results. Therefore, this project can only be done for the chemical that has the above information.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: Identify NHEXAS target chemical to be studied, conduct literature search, assemble data, and design study
	Month	18	(2) Develop and calibrate probabilistic aggregate exposure model; develop regression models to assess correlations between biological and environmental measurements
	Month	12	(3) Final outputs: Exposure assessment, including uncertainty analysis and contributions of various pathways to total exposure
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	60	30	Principal investigator
	80	30 (2)	Senior-level staff ("associate")
	100	30 (2)	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-4. Temporal Variability in Exposure Concentrations and Aggregate Exposure Using NHEXAS Data**
Short Project Description:	Analysis of NHEXAS databases to determine the temporal components of variability in various measures of exposure. The analysis will include both single-medium, single-pollutant class analyses, as well as total or aggregate exposure estimates over all media.
Goal/Objective:	To determine optimum strategies and designs for future NHEXAS national investigations. Questions to be addressed include when is it possible to estimate exposure from a single set of cross-sectional measurements, and what is the optimum number of such measurements that must be made for each pollutant medium class and for total exposure? Of interest is an understanding of the temporal span of the toxicological effect (i.e., what is the exposure duration of interest and does variability occur over such time spans?).

Significance of Project:	A future national investigation of exposures must be designed to assess exposures to members of the population that are accurate and reflect patterns and variability present in true exposures. Improved understanding of temporal variability across days, weeks, and seasons is necessary to ensure good estimates. This project has important implications for risk assessment because it will help account for uncertainty because of statistical "compression" of chronic exposure distributions compared to single-measure exposure distributions because of intraindividual correlations of exposure over time. It also has implications for epidemiology because it will help reduce uncertainty because of misclassification resulting from bias introduced by failing to account for temporal variability in exposure indicators.
Suggested Approach:	(1) Descriptive analysis of exposure concentration distributions by time period. (2) Use statistical techniques to assess population variability and test whether the population means vary over the duration of the studies. (3) Assess intraindividual temporal variability. (4) Evaluate aggregate exposure by summing potential or absorbed doses, as appropriate (with appropriate weighting for time, etc.), over individual pathways. (5) Evaluate temporal variability in total exposure. (6) Assessment of intraindividual variability versus temporal variability in total exposure. (7) Assess statistical strategies for determining optimum sample number for temporal variability. (8) Implement chosen strategy to determine optimum number of exposure measures to determine exposures of fixed length.
Data or Input Needs:	Repeated measurement exposure data for all studies, particularly the NHEXAS-Maryland investigation, identified with specific individual identifiers and temporal spacing. Certain questionnaire data to identify changes in exposure patterns attributable to other-than-usual exposure variability (e.g., a change in job status or introduction of a new source into the home).
Feasibility (of analyses with current NHEXAS databases):	Data exist in the NHEXAS-Maryland study and, to a limited degree, in the other studies, that would allow this to be completed. Repeated measurement data are available for most media in the Region V study. Sample sizes of 2 to 6 repeated measurements are available.

Project Name:	A-4 (cont'd). Temporal Variability in Exposure Concentrations and Aggregate Exposure Using NHEXAS Data		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Prepare databases for analysis of temporal variability
	Month	12	(3) Perform univariate temporal analyses of selected pollutant-class/-medium combinations
	Month	15	(4) Construct aggregate exposure estimates
	Month	18	(5) Evaluate temporal variability in exposure estimates for target chemicals
	Month	18	(6) Construct optimum sampling strategy for target chemicals
	Month	21 24	Final outputs: Intermediate manuscripts on univariate temporal variability Manuscripts on aggregate exposure variability and optimum sampling strategy
Approximate Level of Effort:	% Time	Month s	**Type of Expertise Needed**
	10	24	Principal investigator
	100	24	Senior-level staff ("associate")
	100	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: Information on seasonal trends in environmental concentrations (indoor, outdoor) might help to explain temporal variability.

Project Name:	**A-5. Identifying Predictors of Exposure**
Short Project Description:	To identify primary predictors of exposure, using questionnaires and biological or environmental measures for use in epidemiology studies and other studies where individuals' exposure levels are sorted into categories such as high, medium, and low.
Goal/Objective:	Classification of individuals (and populations) into exposure categories for use in epidemiologic studies and risk assessment. Two products: (1)identify primary predictors of exposure for epidemiologic exposure assessment and (2) identify potentially highly exposed populations for future health effect studies or risk management.
Significance of Project:	Epidemiologists, risk assessors, and risk managers need the ability to classify people into exposure categories. EPA, ATSDR, CDC, NIEHS, and the National Institutes of Health all could use this information.
Suggested Approach:	Using the available NHEXAS data, including questionnaire, biological marker, and environmental data, prioritize chemicals based on the population prevalence or toxicological importance. For the chemicals (or chemical class), construct regression models to identify the predictors of exposure. These analyses should identify which questions predict measured exposure, both biological and environmental. Factor analysis or principal components analysis should be used to identify the most important questions that predict chemical exposure. NHEXAS data should be analyzed to determine how well the environmental data predict exposure and how well questionnaire and environmental measures predict exposure. Predictive models should be developed that can be used in subsequent studies. Key issues would be accurate separation of the population into low, medium, and high categories and development of models to identify highly exposed individuals. Ultimately, efforts should be made to attempt, on an overall basis, to identify which questions identify individuals who are highly exposed to many chemicals and those that are specific for one chemical or one chemical class. Risk managers and study designers will be able to use the results of this analysis to identify sample collection strategies by incorporating predictive ability of the data from each source (questionnaire, biological, and environmental) and the cost to collect and analyze data collected via these methods.
Data or Input Needs:	NHEXAS data from all study sites (or each individually): questionnaires, biological samples, and environmental and personal exposure samples. No additional data needed unless external validation of questionnaire responses is done.
Feasibility (of analyses with current NHEXAS databases):	All data are currently available. Much of the questionnaire data is nominal or ordinal and may not be well suited for the usual regression approaches.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: Assemble data and priorities
	Month	24	(2) Preliminary analyses by chemical/chemical category
	Month	36	(3) Final outputs: Identification of potentially highly exposed individuals and tools to identify them
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	36	Principal investigator
	50	36	Senior-level staff ("associate")

	100	36	Junior-level staff (“assistant”, technician), students (2 to 4) (programmers, epidemiologists, environmental scientists, statisticians)
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-6a. Comparisons of Pollutants and Pathways Driving Cumulative Risks**
Short Project Description:	Assess cumulative risks of various health effects associated with aggregate exposures measured in NHEXAS projects to compare the relative significance of various pollutants and pathways.
Goal/Objective:	To prioritize pollutants and pathways as to their contribution to cumulative risk of various health effects to focus pollution control and other public health activities on higher risk contributors.
Significance of Project:	The results of this project will assist public health agencies (national, state, and local) in effectively and efficiently targeting resources to control pollutants and pathways of higher risk. This project, in conjunction with A1 and A3, will begin laying the foundation for EPA efforts in cumulative (multistressor) risk assessment.
Suggested Approach:	(1) Perform cumulative risk assessment of chemical exposures for individual study participants measured in NHEXAS projects (Use existing EPA guidance and scientific understanding for assessment of mixtures of stressors). (2) Characterize relative contributions to cumulative risk of individual pathways and pollutants per participant and describe distributions across study populations. Report relative contribution of individual pathways and pollutants for representative low-end, average, and high-end NHEXAS subjects. (3) Develop relative ranking of pathways and pollutants in terms of contribution to cumulative risk; identify key driving pathways and pollutants. (4) Compare across studies.
Data or Input Needs:	Exposure measurements from NHEXAS studies. Population descriptions (e.g., body weights, ages, food intakes, etc.) from NHEXAS studies. Toxicity data.
Feasibility (of analyses with current NHEXAS databases):	Limitations include number of pollutants for which quantitative dose-response values are available. Initially, the project probably would consider those chemicals with common health endpoints or modes of action. Also assumptions on nondetects will have to be made (e.g., evaluate using nondetects set to zero versus set to one-half the detection limit (DL) versus omitting large nondetect chemicals from analysis). Cumulative risks would be assessed for variety of health endpoints.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	24	(2) Final outputs: • Multipathway, multichemical assessments with estimates of total risk • Comparison of multichemical risk via single pathways, with total risk for selected NHEXAS compounds • Comparison of risk via single chemical with total risk from selected NHEXAS compounds
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	24	Principal investigator

	25	24	Senior-level staff ("associate")
	100	24	Junior-level staff ("assistant", technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-6b. Use of NHEXAS Data To Test Assumptions about Activity Pattern Factors and Other Exposure Factors in EPA Risk Assessments**
Short Project Description:	This project encompasses a series of individual projects that will examine the use of activity pattern factors and other exposure factors in EPA risk assessments as they are done in the Air, Water, Hazardous Waste, Pesticides, and Toxics Programs. Examples of tasks under this project area were raised at the workshop and include the following: (1) examine NHEXAS time/activity diaries and follow-up questionnaire data to determine the repetitiveness (frequency) of behavior over a 6- or 7-day period and compare to existing time/activity databases used to evaluate factors in EPA assessments, (2) examine the relationship between climate, season, level of exertion, and drinking water intake, (3) prepare exposure scenarios, evaluate scenarios with NHEXAS data, and compare those results to results obtained using current exposure assessment methods, scenarios, and assumptions as they are used in EPA programs, and (4) use NHEXAS data to design scripted sampling protocols for subsequent model testing or trend monitoring.
Goal/Objective:	Current regulatory exposure models in the Air, Water, Hazardous Waste, Pesticides and Toxics Programs often use default values that are based on limited and perhaps unrepresentative data. Often, assumptions are used to fill data gaps. NHEXAS data will be used to test assumptions and scenarios used in current assessment procedures, to improve the current EPA methodologies, and to identify factors where further study is needed.
Significance of Project:	The results of this project area will be useful to any program office that does assessments that rely on factors on which data were collected in the NHEXAS study. These include all EPA programs—Air, Water, Hazardous Waste, Pesticides, and Toxics.
Suggested Approach:	These are examples provided by members of the Assessment Breakout Group: compare 6-day sequences of individual time/activity patterns to 6-day sequences of daily patterns stochastically chosen from multiple individuals to determine impacts and frequency of repeated activities. Assess relationships of individual time/activity patterns to food and water ingestion across subject classes (e.g., age, gender, race) and local climate conditions. Compile individual time/activity and exposure data for subjects with complete data sets as input for exposure model testing and validation. Compile behavioral scenarios characteristic of more highly exposed subjects for use in developing scripted sampling protocols in subsequent exposure model testing and analysis.
Data or Input Needs:	Individual time/activity data and exposure measurements from NHEXAS and other appropriate comparative databases (e.g., time/activity, local meteorological data.)
Feasibility (of analyses with current NHEXAS databases):	Feasible. NHEXAS data set contains data on activity patterns, exposure factors, varying climates, and the like that can be used to test and refine current EPA assessment methods.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration[*]**	**Research Outputs**

	Year	2001	(1) Initiate project: Identify issue to be studied, conduct literature search, assemble data, and design study
	Year		(2) Conduct analysis
	Years	2003	(3) Final outputs: Journal article comparing frequency and duration of various activities over 1-day and 7-day periods in NHEXAS with data collected in other activity pattern surveys
		18 mo	
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	25	18	Principal investigator
	25	12	Senior-level staff ("associate")
	50	18	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-8. Comparison of Children's and Adults' Exposures to Pesticides and Other Chemicals in the Region V, Arizona, and Maryland Studies**
Short Project Description:	Compare children's and adults' exposures to pesticides, VOCs, metals, and PAHs, using biomarker and environmental data collected in the Minnesota Children's Pesticide Exposure Study, Region 5 study, and Arizona and Maryland studies. Data from the children's studies in Arizona and Washington also may be compared as they become available.
Goal/Objective:	To determine if children's exposures differ or do not differ from adults for pesticides and other NHEXAS chemicals.
Significance of Project:	Children have been identified as a potentially vulnerable subpopulation for exposure to pesticides and other chemicals (e.g., lead). NHEXAS data may be used to better understand differences between adults and children's exposures and, ultimately, to determine if federal and state regulatory policies adequately protect children.
Suggested Approach:	(1) Determine what data may be compared (see limitations below). (2) Develop a set of consistent procedures for analyzing the data across studies to take into account between-study differences (e.g., methods for handling values below the detection limit, methods for handling nonnormal distributions, methods for data sets with a large number of values below the detection limit). (3) Compare children's and adults' exposures (where appropriate). Focus on biomarker data (urine and blood) and then expand to diet, personal air, and other measurements. (4) Assess health risks for children and adults using appropriate toxicity values (e.g., RfDs, RfCs, cancer potency slopes). Compare health risks for adults and children.
Data or Input Needs:	Data may be used from the Minnesota Children's Pesticide Study, the Region V study, and the Arizona and Maryland studies. Data from the children's studies that are being conducted in Arizona and Washington also may be included (as the data become available).

Feasibility (of analyses with current NHEXAS databases):	Data between these studies may not be comparable because of differences in types of measurements (chemicals and media), detection limits, methods or strategies of collection, methods of analysis, and spatial and temporal factors. Consistent procedures for data analysis must be developed for comparisons to be valid. Data are available on children for metals and VOCs as well as pesticides. Also need to consider the effects of regional differences on differences between children and adults in different regions. Child subjects in the Region V and Arizona studies possibly might be used to address this, but there may be a limitation based on the number of children in those two studies (about 15%).

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	24	(2) Final outputs: Assessment comparing total exposure (dose) for children in the Minnesota study to total exposure (dose) for adults in Region V or other appropriate studies
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	25	24	Principal investigator
	50	24	Senior-level staff ("associate")
	100	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-9. Indoor, Outdoor, and Personal Air Relationships**
Short Project Description:	This project will evaluate the relationships between indoor and outdoor air concentrations and personal air exposure measurements. Results of these evaluations will provide information to be used in modeling human inhalation exposures to indoor and outdoor sources for use in air pollutant risk assessments (single- or multipollutant). These assessment results will inform public health agencies in evaluating the need to reduce emissions, as well as in prioritizing air pollutants, with regard to relative risks posed by various air pollutants and indoor/outdoor exposures, for the various agencies and offices involved in communicating potential risks and protecting public health.
Goal/Objective:	(1) Evaluate indoor/outdoor air concentration relationships (categorized as appropriate [e.g., urban versus nonurban, seasonal, regional, climatic]) for use in inhalation exposure modeling. (2) Characterize relationship between outdoor air concentrations and indoor air concentrations and personal inhalation exposures and identify key variables affecting these relationships.
Significance of Project:	Assessments of human health risk from indoor and outdoor air pollutants rely heavily on inhalation exposure modeling. Information on the outdoor contributions to indoor air levels are sorely lacking; consequently, assumptions are made (e.g., extrapolation from fixed monitors and air quality models to indoor air concentrations). Additionally, characterization of indoor air pollutant exposures are needed for comprehensive inhalation route risk assessments. This information also is needed to evaluate the uncertainty in exposures in epidemiology studies implicating PM as a cause of adverse effects. Information on the relationship between indoor, outdoor, and personal air concentrations will be used to test assumptions about exposure levels based on fixed monitors.
Suggested Approach:	(1) Perform pollutant-by-pollutant and multichemical pairwise analysis of outdoor and indoor concentrations, outdoor concentrations and personal exposures, and indoor concentrations and personal exposures. (a) subdivide analyses via spatial/source considerations (e.g., urban/rural, smoker/nonsmoker) that are key drivers of pairwise relationships. (2) Develop pollutant-by-pollutant distributions of indoor/outdoor concentration ratios, (a) subdivide distributions based on spatial/source considerations (e.g., urban/rural, smoker/nonsmoker). (3) Identify fixed monitors in study sites and evaluate correlations of study measurements (outdoor, indoor air, and personal exposure) to fixed monitor measurements in each study area. (a) identify variables that may play a role in variation in these relationships (e.g., urban/rural, etc.).
Data or Input Needs:	NHEXAS: Indoor air measurements Outdoor air measurements Personal exposure measurements Some activity data to help understand personal exposure data (e.g., time outdoors, time indoors, time near particular sources) Sample dates, geographic locations, sampling protocols Other: Fixed air monitor sites and data in study site
Feasibility (of analyses with current NHEXAS databases):	Good, assuming the availability of sets of measurements with sufficient percentage of samples above the detection limit where the same particle size fraction was collected.

Project Name:	A-9 (cont'd). Indoor, Outdoor, and Personal Air Relationships		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month		(2) Relationships (e.g., pairwise analyses)
	Month		(3) Identification of fixed monitors, categorization of data via important variables (e.g., smoker/nonsmoker, urban/rural, etc.)
	Month		(4) Final outputs: Pollutant-by-pollutant indoor:outdoor ratios
	Month		(5) Final comprehensive report/papers
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	18	Principal investigator
	10	18	Senior-level staff ("associate")
	200	18	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-10. Comparison of Traditional Indirect Method of Estimating Dietary Exposures to NHEXAS Duplicate Diet Data**
Short Project Description:	Comparison of exposure data from NHEXAS duplicate diet measurements with exposure estimates indirectly derived based on combining food intake rates and data on concentrations of NHEXAS chemicals in food from studies such as the Total Diet Study (TDS). Also compare food intake rates from NHEXAS questionnaire surveys with those from USDA and NHANES food intake surveys of comparable years, geographical regions, and population subgroups
Goal/Objective:	Compare dietary exposure estimates from the dietary exposure model (i.e., concentration in food × reported food consumption rates) with direct measures of dietary exposure obtained from NHEXAS duplicate diet sampling.
Significance of Project:	Dietary exposure based on the indirect method of combining food intake with residue data has been the cornerstone of many pesticide regulations. In addition, estimates of human exposure to metals and other chemicals through food consumption have been based on this indirect approach. Although this model approach to dietary exposure assessment is widely used, validation of such estimates with real monitoring data have not been done. NHEXAS data provided an opportunity for such validation to enhance the scientific bases for decision making. Such validation would help to direct future efforts in dietary exposure assessment.
Suggested Approach:	(1) Code food intake data from NHEXAS food diary or food checklist into formats that are consistent with USDA food codes. (2) Compare NHEXAS food intake rates with those from USDA and NHANES for comparable time frames, regions, and population subgroups, including evaluation of weighting for nonresponse, single-day intakes versus averaging intake over several days (where data allow such evaluation). (3) Estimate exposure based on consumption data and residue data from FDA TDS, USDA Pesticide Data Program (PDP) data, NHEXAS Maryland minimarket basket survey, and other existing residue data. (4) Estimate exposure using NHEXAS food diary or checklist data and existing concentration data from other sources and compare results with results obtained with indirect method across population subgroups. (5) Estimate exposure using NHEXAS duplicate diet measurements and compare these results with results obtained from indirect method across population subgroups.
Data or Input Needs:	NHEXAS food diary and checklist data and duplicate diet data from each study. USDA and NHANES food intake data and codes. USDA and Food and Drug Administration (FDA) food contaminant data. The food diaries have not been coded and it may not be possible to code to all the USDA codes. The food checklist is limited to 100 to 200 food items. The big discrepancy between number of items that could make cross-coding difficult.
Feasibility (of analyses with current NHEXAS databases):	The duplicate diet studies and diet questionnaires were administered to a sufficiently large number of individuals in the Region V and Arizona studies to support these analysis. In addition, the Maryland data obtained food intake longitudinally to allow an in-depth comparison of short- and long-term average intake.

Project Name:	A-10 (cont'd). Comparison of Traditional Indirect Method of Estimating Dietary Exposures to NHEXAS Duplicate Diet Data		

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project
	Month	6	(2) Harmonizing food codes between NHEXAS, USDA, and NHANES
	Month	9	(3) Compare food intake rates between the various surveys
	Month	12	(4) Estimate exposure based on intake rates and residue data
	Month	18	(5) Compare exposure from NHEXAS duplicate diet studies with those obtained from indirect method
	Month	24	(6) Final outputs: Report consistency or inconsistency between the two approaches and identify approaches (if any) to improve the indirect method of estimating dietary exposure
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	15	24	Principal investigator
	35	24	Senior-level staff ("associate")
	50	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-11. Improved Methods for Collecting Data for Exposure Assessments**
Short Project Description:	Compare or link methodologies and results between and within the NHEXAS studies to determine potential improvements in techniques or procedures currently used in human exposure studies. Topics include (but are not limited to): (1) establish potential for NHEXAS chemicals to be used as tracers to indicate the contribution of ambient air to indoor air concentrations, (2) evaluate questionnaire implementation procedures, (3) evaluate environmental and biological sampling, and (4) evaluate food frequency survey methodology and compare to national food consumption methodology.
Goal/Objective:	To improve current techniques or procedures used to measure human exposure and the factors that contribute to exposure.
Significance of Project:	Critical to designing future studies using more cost effective methods.
Suggested Approach:	(1) For chemicals with only outdoor sources, determine (model) how indoor concentrations relate to outdoor sources. Establish potential for these chemicals to be used as tracers to determine the contribution of ambient air to indoor air concentrations. (2) Compare across and within the NHEXAS studies, the study design, incentives, procedures used to implement the questionnaire, and the like. Evaluate differences and similarities in response rate and reliability of responses in relation to procedural differences. Evaluations should consider regional, socio-economic, education and other demographic issues as appropriate. (3) For contaminants or biological factors tested in more than one study, compare any differences in methodology or implementation techniques and evaluate how these differences may have positively or negatively impacted results. (4) Investigate the use of the food frequency data from the NHEXAS study as a bridge with the USDA food intake data and data from future surveys to improve the information available for estimations of food intake. (5) In the Maryland study, evaluate whether participants improved in filling out questionnaires through repetition or deteriorated as a result of fatigue.
Data or Input Needs:	(1) Basic distribution statistics of NHEXAS data. (2) Full procedural descriptions of each study. (3) Meta data for NHEXAS (sampling and analytical protocols, study designs, etc.).
Feasibility (of analyses with current NHEXAS databases):	High

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: Identify issue to be studied, conduct literature search, assemble data, and design study
	Month	6	(2) Conduct analysis
	Month	12	(3) Final outputs: Journal article (e.g., an article discussing the utility of various NHEXAS analysis to serve as tracers to quantify the infiltration of outdoor air to the indoor environment)

Approximate Level of Effort:	% Time	Months	Type of Expertise Needed
	25	12	Principal investigator
			Senior-level staff ("associate")
	100	12	Junior-level staff ("assistant", technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**A-12. Spatial Variability**
Short Project Description:	NHEXAS data will be used to investigate spatial variability in concentrations, doses, and activity patterns. Possible areas of investigation include different states and counties, rural versus urban areas, locations near sources, and different climates and elevations.
Goal/Objective:	The goals of this research are to identify spatial and geographic factors contributing to high exposures for consideration in exposure assessment, to determine representativeness of local/regional data for use in assessments of other regions, and to identify geographically defined point and area sources.
Significance of Project:	These analyses will help assessors understand the geographic variability of pollutant concentrations and exposures and the impacts of such things as population density, climate, elevation, and local cultural factors. It also will examine the impact of identifiable, geographically located sources on exposure levels. Information on spatial variability also will contribute to more efficient design of future studies.
Suggested Approach:	(1) The following is an approach for comparing different geographical areas: select variables for comparison (e.g., a particular chemical/media combination), consider differences in sampling methodology that could account for differences between NHEXAS studies, account for confounding factors, and make statistical comparisons of distribution parameters. (2) The following is an approach for analysis of sources: identify potential sources of NHEXAS chemicals based on other data, such as data in the literature and the EPA Toxic Release Inventory Data; and perform analysis of correlation of exposure concentrations and locations of sources using geostatistical methods.
Data or Input Needs:	(1) Sufficient number of people in each geographic group to make meaningful comparison. Data set needs to have sufficient percentage of detectable levels of NHEXAS target chemicals. Sampling protocols and equipment for each location need to be similar enough so that differences are not attributable to the methods used. (2) Independent database to provide latitude and longitude and perhaps some estimate of emissions for target sources. Latitude-longitude and concentration/exposure data for NHEXAS participants.
Feasibility (of analyses with current NHEXAS databases):	(1) This study could be done for a few categories (e.g., state-by-state) in Region V. There may be a problem comparing environmental samples between studies because of different sampling methodologies. Parameters selected for comparison need to have similar sampling protocols (e.g., blood, urine, drinking water, etc.). (2) Data on latitude and longitude of sources is critical as is data on latitude and longitude of participants (may be available only for Arizona). There also would need to be some method to protect the confidentially of respondents that could be compromised by revealing the latitude-longitude of their residences.

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project: Identify issue to be studied, conduct literature search, assemble data, and design study.
	Month		(2) Conduct analysis
	Month	24	(3) Final outputs: Comparison of measurements, activity pattern duration/frequency, or total exposures in different geographical areas. Description of similarities and differences between sampling and analytical methods of NHEXAS consortia and potential impact on comparisons of results.
Approximate Level of Effort:	% Time	Month s	**Type of Expertise Needed**
	10	24	Principal Investigator
	25	24	Senior-level staff ("associate")
	50	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	A-13. Analysis of NHEXAS Questionnaire and Activity Diary Data to Identify Temporal Trends in Behavior and Exposure Patterns
Short Project Description:	Comparison of NHEXAS activity pattern data to past studies such as TEAM, NHANES, and the National Human Activity Pattern Survey (NHAPS) to identify any temporal trends in activity patterns that may be important predictors of changes in exposure patterns over time.
Goal/Objective:	To identify changes in behavior over time that can explain changes in exposure patterns.
Significance of Project:	Identifying temporal trends in behaviors that have an impact on exposure can lend insight into the success of intervention strategies (such as increasing public awareness of environmental hazards). The SAB/IHEC recommended such evaluations. In addition, studying temporal trends in behavior and exposure can inform the selection of future intervention strategies and help to evaluate their performance and ultimate results.
Suggested Approach:	(1) Use questionnaire and diary data from all studies to develop activity specific distributions. (2) Compare activity distributions from the NHEXAS study to past studies, noting any shifts in important parameters. (3) Identify factors (qualitative) that could explain the shift in behavior (e.g., a home use pesticide product was removed from the market between the NHAPS and NHEXAS studies).
Data or Input Needs:	Questionnaire and diary data from each of the studies involved in the comparison. Identification of the codes used for questions that are the same (or similar) in each study.
Feasibility (of analyses with current NHEXAS databases):	Feasibility depends on the availability of similar questionnaire data in the historical studies. Availability of such data judged to be unlikely. There may be a problem with the timing of data collection.

Approximate Project Time Table and Level of Effort			
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Build questionnaire databases and develop activity specific distributions
	Month	12	(3) Make comparisons between distributions and prepare analyses.
	Month	18	(4) Identify factors contributing to shifts in behavior
	Month	24	(5) Final outputs: Produce report documenting temporal trends in activity patterns that are important for changes in exposure
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	24	Principal investigator
	25	24	Senior-level staff (“associate”)
	50-100	24	Junior-level staff (“assistant”, technician), Students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

4.3 EXPOSURE ANALYSIS GROUP

This group focused on research that advances the state-of-the-science of exposure analysis. It covers such issues as descriptive/demographic analyses, associations/models of internal dose, associations/models of exposure, and methods.

4.3.1 SAB Comments

The SAB identified several issues relating to analyses of exposures and the development of a strategic plan for data analysis [3.2.2.a][2] that are described below.

(1) Complete quality assurance and quality control (QC) of the study data. [3.2.2.a]

(2) Conduct descriptive analyses.

(3) Test study hypotheses that can be addressed with the collected data. [3.2.2.e]

(4) Evaluate questionnaires and activity diaries and the relationships between these data and environmental, exposure, and biomarker measurements. [3.2.2(b,c)]

(5) Critically evaluate the potential value of meta-analysis across the three consortia, given limitations because of differences in study designs and methods. [3.2]

(6) Integrate total exposures across all media, and assess the relative contribution of different sources, pathways, routes to exposure, and body burden. [3.2.2(c,d,g)]

(7) Estimate long-term exposures from short-term measurements. [3.2.2(d,g)]

(8) Identify factors related to high-end exposures and correlate exposure to various chemicals/classes. [3.2.2.g]

4.3.2 Questions To Address

As a starting point to identify, describe, and prioritize potential projects, the breakout group should consider the following question and formulate a list of specific analyses for further discussion.

What analyses need to be done? These might be identified by the types of analyses (or intended use of the results).

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[2]Numbers in brackets are cross-references to sections in the SAB report.

(1) Descriptive (in addition to those conducted by/for each study)

- Summary statistics
- Distributional analyses (or fitting)
- Weighted and unweighted analyses

(2) Comparative

- Hypothesis testing (including study design hypotheses)
- Exploratory analyses (hypothesis generating)
- Results of analyses conducted by each study (combine data sets or results)
- Structural (model-based) analyses of exposure (or dose)
- Temporal analysis
- Within- and between-season (visit, cycle)

(3) Grouping or classification analyses

- For future human exposure surveys and epidemiological studies
- Identification of factors related to the "high-end" of exposures

(4) Questionnaire analyses

- Item analysis (association between responses, reliability)
- Internal and external consistency (validity)
- Cross-study comparisons

(5) Survey design results

- Estimates of variance components (e.g., geographic clustering, correlation between chemicals/classes and measurements)
- Use of variance estimates and design effects to determine sample sizes for estimating median populations and population subgroup exposures

(6) QA/QC data analyses

- Calculation of data quality parameters (e.g., precision, bias, quantifiable limit, or method detection limit)
- Identification of QA goals and performance measures

4.3.3 Discussion Considerations

In discussing and developing proposals for the analyses (or projects) identified above, consider the following questions.

(1) What statistical approaches or techniques could (or should) be used to understand or explore relationships among the following types of measurements or information?

- Environmental/individual characteristics (questionnaires)
- Environmental concentrations
- Human activity patterns
- Human exposures measurements (or estimates) for multiple routes and pathways
- Estimates of intake or uptake (dose) that are derived from concentration or exposure measurements and activity data or exposure factors
- Biological markers of exposure (and total absorbed dose)

(2) Which of these are feasible and appropriate, given the understanding of the study and survey designs?

C Types of samples and questionnaire data that were collected in the current NHEXAS projects

C Quantity and quality of these results (e.g., based on response and completion rates, and proportion detectable/measurable)

C Limitations for combining data sets (or results) to permit meaningful joint (or meta-) analyses

(3) What are the top priority/most important analyses? These might depend on the intended application.

C For exposure or risk assessments

C To advance our understanding of multi-pathway human exposure (and dose)

C For designing future human exposure studies

4.3.4 Brainstorming List of Projects

Descriptive/Demographic Analyses
Meta-analysis of exposure parameters and biomarkers of dose for children, adults, and elders
Comparing distributions of "total exposure" by population subgroups
Epidemiology of biomarkers, pathways, and media (compare distributions in different subgroups)
Identification of susceptible populations (for high exposure) and comparison with other studies
Spatial and temporal variability in multichemical exposure and risk
Evaluation of upper percentiles in three exposure studies with chemical exposure levels associated with health effects
Meta-analysis of heavy metal exposures from NHEXAS and other surveys
Comparison of NHEXAS exposure levels with other studies (creation of baseline or benchmark exposures and reference ranges)
Consistency of demographic data with other representative population surveys
Principle component analysis for grouping biomarker, environmental concentrations, and questionnaire information
Clustering of exposures from different media (concentrations and questionnaire information)
Associations/Models of Internal Dose
Multivariate analysis of risk factors for internal exposure–demographics, questionnaire data, and measures of external exposure
Health indicators for differences in exposure
Contribution of environmental media to body burden and clearance of chemical pollutants
Relation of biomarkers of dose to reported illnesses
Associations/Models of Exposure
Association between exposure measurements and housing or activity factors (sources and removal)
Characterization of indoor dust and soil measurements (relationship to exposure)
Multivariate (logit) analysis and comparison of exposure to activity patterns and environmental concentrations
Questionnaire elements that predict high-end exposures
Long-term exposure related to short-term measurements
Multichemical exposures to chemicals with similar mechanism of action and health endpoints
Aggregate exposure to pesticides–ranking of pathways
Population modeling analysis of high-end exposures in Arizona and Region V NHEXAS (for risk assessment)
Methods
Differences and similarities in dietary exposures estimated by the Maryland checklist, compared with the diet diary and duplicate diet approach
Comparison of duplicate diet measurements with model estimates based on extant food contaminant data combined with individual consumption
Relation between intra- and interindividual variability in exposure metrics and different time scales; implications for risk assessment and environmental epidemiology

Methods (cont'd)
Comparison of the approaches used to collect longitudinal data, Region V, Maryland)–selection of future methods
Modeling/estimation of THMs in NHEXAS from the chloroform measurements, based on data from other national studies
Analysis of the impact of different measurement sensitivity DL or quantitation limit and censored data on estimates of total exposure
Comparison of modeled to measured estimates of exposure
Critical pathway analysis (risk from exposure) for three studies–how to combine results, findings
Potential use of NHEXAS pilot study data to estimate national exposure distributions
Cost-benefit analysis of the value of alternative exposure measurements relative their costs in reducing uncertainty in exposure models
Estimation of dermal exposure from NHEXAS data

4.3.5 Project Descriptions

Project Name:	**EA-01. Analysis and Comparison of NHEXAS Exposure Data to Residential Pollutant Sources and Activity Patterns**
Short Project Description:	Analysis of questionnaire, time/activity, environmental, and exposure data collected in the three NHEXAS studies to determine the associations between measured exposures and pollutant sources, housing characteristics, and human activities (e.g., the relationship between the use of cleaning supplies and VOC exposures; the characterization of residential dust and soil measurements; and the relationship to personal exposure monitoring).
Goal/Objective:	To evaluate and identify hypotheses about those residential pollutant sources, housing characteristics, and activity patterns that contribute to human exposures, especially high-end exposures.
Significance of Project:	To provide policymakers with information to develop guidance for reducing exposures by both modifying pollutant sources and housing characteristics and educating the public about how their activities contribute to exposure. In addition, the project will help researchers refine the questions to be asked and pollutant measurements to be made in subsequent similar studies. Identification of associations with questionnaire information also is useful for classification of exposures in epidemiological studies.
Suggested Approach:	(1) For each of the NHEXAS pilots, explore associations between residential pollutant sources, concentrations, and exposures; housing characteristics, concentrations, and exposures; concentration measurements in different media; and human activities, concentrations, and exposures. (2) Compare these results among the three studies. (3) Conduct multivariate analysis to determine the combined impact of residential pollutant sources, housing characteristics, and activity patterns on exposures.
Data or Input Needs:	For all three studies, measured concentrations in all media, exposure activity information (diaries and questionnaires), housing characteristics, and occupational data.
Feasibility (of analyses with current NHEXAS databases):	Need to review availability of samples for some media, proportion of analyses above detection limits, and substitution of measurements obtained from nearby households during the same periods of time (e.g., for outdoor air and soil measurements in Region V study).

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Develop analysis plan
	Month	12	(3) Complete multivariate analysis of individual NHEXAS pilots
	Month	15	(4) Compare analysis among studies to help combined study analysis
	Month	24	(5) Final outputs: Complete combined study multi-variate analysis and final report
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	25	24	Principal investigator
	25	24	Senior-level staff ("associate")
	100	36	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Association/Models of Exposure.

Project Name:	**EA-02. An Analysis of Media Concentrations, Exposure, and Biomarkers by Population Demographics**
Short Project Description:	Descriptive analysis of media concentrations, exposure, and biomarker measurements for population subgroups (age, gender, ethnicity, socio-economic status [SES], urban/rural, or other important groupings) for each NHEXAS study.
Goal/Objective:	To provide a descriptive analysis of media concentrations and biomarker measurements by population characteristics in order to identify susceptibility factors and differences among groups and to compare distributions with other studies.
Significance of Project:	(1) Will serve as basis for planning and interpretation of NHEXAS data and to identify subpopulations for further study. (2) Provides baseline information for comparison to other locations such as Superfund sites and to assess trends. (3) Useful to EPA and others doing analysis of NHEXAS data and for planning further studies
Suggested Approach:	Statistical comparison of weighted distributions (frequency, means, etc.) by population subgroups (from questionnaire data) for media concentrations, biomarkers, and exposure to assess differences and similarities between or among subgroups.
Data or Input Needs:	Questionnaires and time/activity data from each of the studies. Biomarker and environmental measurements data from each study. Detection limits for environmental chemicals from each study. Population weights and stratification variables.
Feasibility (of analyses with current NHEXAS databases):	Data currently exists, questionnaires are the same across groups, comparability of analytic results will be assessed using information about detection levels. There is concern over the level of stratification (limited cell sizes) that can be achieved because of measurements below detection and incomplete sampling of some media (e.g., subsampling of homes for outdoor air measurements).

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Identify those chemicals for which there is adequate data for analysis; determine strata to be used in analysis
	Month	24	(3) Final outputs: Manuscript, tables, and graphs of distributions by strata, and completed statistical analysis and interpretation
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	15	24	Principal investigator
			Senior-level staff (“associate”)
	50	24	Junior-level staff (“assistant”, technician), students
	50	24	Other (describe): Second student

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Descriptive/Demographic Analysis.

Project Name:	**EA-03. Risk Factors for Biomarkers of Internal Dose: Demographics, Questionnaire Data, Concentrations, and Exposures**
Short Project Description:	Analyses to determine the association of biomarkers of internal dose with (1) demographic characteristics; (2) questionnaire information on behaviors, activity patterns, health indices, etc.; and (3) measures of personal exposures and media concentrations.
Goal/Objective:	To develop simple methods of estimating internal dose that can be used in studies of health outcomes.
Significance of Project:	Analytic or epidemiologic studies of health endpoints need effective methods for estimating internal dose, but direct measurement is often impractical. For example, studies of chronic health effects may require estimates of long-term average or historical exposures. NHEXAS provides a rich source of information that allows inferences about internal dose based on data collected from questionnaires, measures of chemicals in external media, and other sources.
Suggested Approach:	For appropriate chemicals and classes of chemicals: (1) Bivariate analyses of the association of biomarkers of internal dose and risk factors, including demographics, housing characteristics, questionnaire data, and measures of exposure. (2) Examine correlations among risk factors. (3) Multivariate modeling of the association of biomarkers with risk factors.
Data or Input Needs:	Biomarker concentrations, demographics, questionnaire data, and environmental media concentrations and exposure measurements.
Feasibility (of analyses with current NHEXAS databases):	These analyses will be feasible only for chemicals where biomarkers of internal dose exist at detectable levels for a sufficiently large sample. For a given risk factor, there also must be sufficient variability. Also requires knowledge of biomarker characteristics (e.g., half-life) to relate measurements to time of exposures.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Conduct bivariate analyses
	Month	12	(3) Examine interrelationships of covariates
	Month	24	(4) Final outputs: Results of multivariate modeling
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	5	24	Principal investigator
	50	24	Senior-level staff (“associate”)
	200	24	Junior-level staff (“assistant”, technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Associations/Models of Internal Dose.

Project Name:	**EA-04. Estimation of Dietary Exposure and Comparison of Methodologies Utilized in NHEXAS**
Short Project Description:	Direct estimates of dietary intakes by duplicate diet for various contaminants will be analyzed to describe, compare, and evaluate the validity, reproducibility, and cost effectiveness of the collection methods relative to indirect estimates based on the combination of consumption (reported in the diary or checklist) and extant data from other sources (e.g., TDS, NHANES, etc.).
Goal/Objective:	To estimate the reliability and validity of the dietary intakes for several of the contaminants included in NHEXAS and to evaluate the value added over estimates derived from extant data. To evaluate alternative and less costly methods for measuring dietary exposure relative to the duplicate diet approach.
Significance of Project:	Addresses several issues related to analyses of exposures including testing of hypotheses (adequacy of extant data and models to predict exposure), evaluation of survey instruments, and prediction of dietary exposure as a component of total exposure. Comparison of dietary measurement and estimation approaches may help to identify less costly alternatives for dietary exposure monitoring, and to provide estimates of long-term exposures from short-term estimates.
Suggested Approach:	(1) Calculate dietary exposures using consumption data (diary or checklist) and extant food contaminant data. (2) Comparisons of calculated exposures with measured duplicate diets. (3) Comparative analysis of dietary data from checklist, duplicate diet collection, and mini-market basket approach in terms of validity, reliability, and cost effectiveness. (4) Analyses of calculated dietary exposures in relation to various demographic variables.
Data or Input Needs:	Individual dietary consumption records, coding of food consumption to USDA or EPA/Dietary Exposure Potential Model (DEPM) codes, duplicate diet measurements from each consortia, existing food contaminant data for those target chemicals measured in diet samples (from DEPM).
Feasibility (of analyses with current NHEXAS databases):	High, as soon as the verified databases are available on each of the above parameters. May be limited to quality/resolution of dietary consumption and duplicate diet measurement data.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3-6	(2) Determine the compatibility of the data sets
	Month	6-12	(3) Formulate and test methods of statistical analyses
	Month	18	(4) Final outputs: Reports/manuscripts of estimated dietary exposures
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	25	18	Principal investigator
	100	18	Senior-level staff ("associate")

	50	12	Junior-level staff (“assistant”, technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Methods.

Project Name:	**EA-05. Spatial and Temporal Variability in Multichemical Exposure**
Short Project Description:	Project will better characterize the magnitude and variability in exposure to multiple chemicals measured in all environmental media by the three NHEXAS studies for different locations of the country. Both within- and between-study variability will be examined, and analyses will be conducted to determine whether exposure to one chemical in a given class is predictive of exposures to other compounds in that class or other classes.
Goal/Objective:	The goal of this project is to provide information that will improve the efficiency (e.g., cost-effectiveness) of future exposure, risk assessment, and epidemiologic investigations of health risks of cumulative chemical exposure. This study will provide some of the first information on multichemical and multipathway exposures required for cumulative risk assessments.
Significance of Project:	The need to assess risks of cumulative chemical exposures is well recognized within the scientific and regulatory communities. Little information is available for such assessments. Analysis of the temporal and spatial aspects of the NHEXAS data is important to reduce uncertainty in the exposure estimates for these assessments.
Suggested Approach:	The suggested approach is to examine multiple chemical exposure, first for each route of entry and second for aggregate exposure. This approach should be limited to two or three chemical classes, but utilize all of the NHEXAS data even if a compound was not collected in all media (e.g., VOCs). Analyses will be performed on measurements of environmental concentrations, exposure, and biomarkers (related to internal dose). Investigators should determine the appropriate chemical classes for study.
Data or Input Needs:	Concentration, exposure, and biomarker measurements from each NHEXAS study.
Feasibility (of analyses with current NHEXAS databases):	The feasibility of the proposed project is high for analyses of data within the Maryland study. Some limitations are anticipated in the types of samples available from the Region V study. (Longitudinal samples were not collected for Arizona.)

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: Identification of common variables across studies
	Month	12	(2) Initiate investigations within each medium and combine data across media where feasible for each study
	Month	24	(3) Complete single-route and aggregate analyses of cumulative exposure

	Month	36	(4) Final outputs: • Compare findings between studies • Report findings, write reports and manuscripts on cumulative chemical exposure.
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	36	Principal investigator
	25	36	Senior-level staff ("associate")
	50	36	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Descriptive/Demographic Analyses.

Project Name:	**EA-06. Comparison of Cross-Sectional and Longitudinal Variability in Exposure Metrics: Implications for Study Design**
Short Project Description:	This project will provide for the analysis of the variability in media concentrations, exposures, and doses over space and time among and within the NHEXAS studies. It will examine the variability of exposure distributions based on short-term measurements compared to those based on long-term measurements or averages and determine the reliability of a short-term measure of exposure for assessment of long-term exposure for populations and individuals.
Goal/Objective:	The goal of this project is to provide information that will improve the efficiency (e.g., cost-effectiveness) of future exposure, risk assessment, and epidemiologic investigations. Such information will allow for improved selection of sample size (number of subjects), sample type (concentration, exposure, or dose), and number of repeated measurements per subject in cross-sectional and longitudinal studies.
Significance of Project:	Little information is available to aid in the design of studies intended to assess risk of acute and chronic exposure to environmental pollutants. Analysis of the temporal and spatial aspects of the NHEXAS data is anticipated to provide information suitable for this purpose.
Suggested Approach:	Analyses will be performed on measurements of environmental concentrations, exposure, and internal dose. This approach should be limited to two or three chemicals for which there are measures of all three metrics (e.g., arsenic, chlorpyrifos, benzene). Between- and within-person variability of exposure will be assessed and compared within and across NHEXAS studies.
Data or Input Needs:	Concentration, exposure, and dose measures from each NHEXAS investigation.
Feasibility (of analyses with current NHEXAS databases):	The feasibility of the proposed study is high for analyses of data within a NHEXAS study. Some limitations are anticipated for analysis of data across the different NHEXAS investigations.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***	**Research Outputs**

	Month	0	(1) Initiate project
	Month	12	(2) Initiate investigations within a study and combine data across studies where feasible
	Month	24	(3) Complete within-study analyses and continue analysis of data combined across studies
	Month	36	(4) Final outputs: Report findings, write reports and manuscripts on the implication of temporal and spatial variability for improved study design
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	36	Principal investigator
	25	36	Senior-level staff ("associate")
	50	36	Junior-level staff ("assistant", technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Methods.

Project Name:	**EA-07. Impact of Censoring and Method Sensitivity and Precision on Multimedia Exposure Distributions and Associations**
Short Project Description:	This study will examine how method sensitivity and precision, and the censoring of data below detection limits, affect the estimation of distributions and means for exposure, media concentration, and biomarker measurements; and the evaluation of associations among such measurements. To the extent possible, intakes will be used in order to make the assessment on a total exposure basis.
Goal/Objective:	To investigate the degree to which the NHEXAS goal of measuring total exposure may be limited by the method precision, sensitivity, and censoring of data below DLs.
Significance of Project:	A major goal of NHEXAS was to estimate exposure through multiple routes, especially for those most highly exposed. This goal may be limited by the proportion of measurements that are below DLs for some target analytes and media and because method sensitivities differed across both media and studies. This project will be valuable in determining methods and approaches for conducting future NHEXAS or other multimedia human exposure studies.
Suggested Approach:	(1) Determine the percent of measurements above DLs, and the availability of health thresholds and QC data in order to focus the study on the most relevant media and chemicals. (2) Use uncensored results where available and impose censoring on them (i.e., set values <DL to missing or to some predefined value); compare distributions for the uncensored and censored cases. (3) Use QC (duplicates) data to estimate measurement error variability; generate simulated data that one would expect using another method with more or less precision; summarize/compare the distributions. (4) To the extent possible, evaluate the impacts of steps 2 and 3 both in terms of intakes and of total exposure. (5) Investigate ways of assigning values to measurements that are below DLs.
Data or Input Needs:	Physical measurements from all three studies. (Summaries of distributions and DLs may be used to conduct simulations for intake estimates and for evaluating uncertainties associated with measurements <DLs.) QC data.
Feasibility (of analyses with current NHEXAS databases):	Will be practical and relevant only for some types of measurements (i.e., those with more complete collection of exposures or environmental media for multiple pathways). The selection of measurement and analysis methods for NHEXAS were based on quantifying exposures at the “high-end” of the distribution, which may limit the availability of measurements above detection limits for all media.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Evaluate scope/relevance of project with respect health thresholds, availability of data, degree of nondetects, etc.
	Month	9	(3) Perform analyses, simulations and prepare draft manuscript
	Month	12	(4) Final outputs: Complete final manuscript
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	15	12	Principal investigator

			Senior-level staff ("associate")
	35	8	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Methods.

Project Name:	**EA-08. Providing Improved Exposure Models Using Cost-Effective Approaches**
Short Project Description:	Comparison of uncertainty in exposure estimates obtained using different types of measurements or other data (e.g., screening measurements or questionnaires) with those based on the more intensive direct exposure measurements conducted in NHEXAS. In addition, comparisons of costs and uncertainty will be made between direct exposure measurements and indirect estimates based on existing data and models.
Goal/Objective:	To assess the cost and uncertainty differences between exposure models using screening level measurements, questionnaire information, nonprobability samples (i.e., purposive samples), and existing exposure-related data relative to the NHEXAS measurements and study designs.
Significance of Project:	Clearly, multimedia, multipathway studies are needed. This study will help to identify the incremental differences in model performance associated with more detailed (sensitive and accurate) methods, and with representative population samples–relative to more focused stratified or specialized substudies. Stratification can be based on SES characteristics, inexpensive screening techniques or any other means deemed appropriate. Resources are limited, and great care must be taken to wisely allocate them. This study will provide information to help determine (1) how to minimize exposure measurement costs for a national study, (2) how to prioritize resource allocation, and (3) approaches with the necessary utility and accuracy for specific exposure assessment studies.
Suggested Approach:	Build multiple models and compare them. (1) Comparison of exposure models derived from existing measurement data (or questionnaire data) contrasted with models using new subject-specific chemical measurements, characteristics, and activities (i.e., NHEXAS). (2) Comparison of exposure models derived from data with different sensitivities (e.g., questionnaires and screening measures with differences in analytical performance).
Data or Input Needs:	Example for Approach 1: Use existing Aerometric Information Retrieval System data to model residential concentrations and exposures, and compare with measured Region V indoor/outdoor and personal air data; existing TDS concentrations used to model dietary intake, and compare with duplicate diet measurements. Examples for Approach 2: Comparison of Arizona XRF data compared with (ICP/mass spectrophotometry) data (Arizona study); comparison of questionnaire-based models with measurement-based contaminant models. Exposure and intake models from each study.

Feasibility (of analyses with current NHEXAS databases):	Limitations include equivalency in terms of temporal and geographic variability, SES/demographic/population variability/representativeness, collection and analytical methods.

Project Name:	**EA-08 (cont'd). Providing Improved Exposure Models Using Cost-Effective Approaches**		

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Identifying relevant data sets and obtaining data sets
	Month	12	(3) Generating comparison-compatible data sets
	Month	12	(4) Obtaining models from each NHEXAS study for comparison
	Month	24	(4) Analysis and summary of results
	Month	30	(6) Final outputs: Three or more published papers
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	30	Principal investigator
	50	30	Senior-level staff ("associate")
	100	18	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Methods.

Project Name:	**EA-09. Analysis of Variable Groupings in the NHEXAS Data Sets for Evaluating the Usefulness of Questionnaires for Exploring Relationships Between Exposure, Dose, and Risk Factors**
Short Project Description:	The NHEXAS databases include a wide spectrum of measurements: questionnaire responses, exposure measurements, and dose/biomarker measurements. These data will be analyzed without a priori decisions about relationships among the variables to generate new hypotheses regarding environmental exposures.
Goal/Objective:	Identifying and evaluating associations among the NHEXAS variables. This goal is related to the multivariate analyses called for in proposals EA-1 and EA-3 and understanding differences and similarities among subpopulations (EA-2).
Significance of Project:	Classification of NHEXAS data into variable groups will help focus future exposure assessments in national surveys, epidemiological studies, and risk assessments. (It also provides a comparison between the questions and the rationale for their use.)
Suggested Approach:	The strengths and limitations of the data will be evaluated initially using univariate analyses of individual variables. Next, a multivariate classification technique will be selected and run (e.g., principal components, classification and regression trees [CART], or factor analysis) to identify groupings of variables. The groups will be evaluated in order to generate hypotheses, to guide in the design of other studies, and to identify important questions and/or measurements for future exposure assessments and risk assessments. Analyses are to be conducted by pertinent subpopulations because the variables may group differently by subpopulation.
Data or Input Needs:	Database of complete measurement data including all chemical measurements and questionnaire responses.
Feasibility (of analyses with current NHEXAS databases):	Feasibility of the project will be limited by the number of observations within strata.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Univariate analyses
	Month	12	(3) Final outputs: Final report and journal article
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	12	Principal investigator
	50	12	Senior-level staff ("associate")
	25	12	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:

Classification: Descriptive/Demographic Analyses.

Project Name:	**EA-10. Determinants of Dose Measurements (Biomarkers) from the NHEXAS Studies**
Short Project Description:	Absorbed dose may be estimated by questionnaire and measurement data including air, water, diet, and contaminated surfaces. Predictive associations between measurements of exposure and dose will be evaluated. Questionnaire response data will be considered as a modifier of the exposure/dose association. This association will be evaluated further by taking into account existing pharmacokinetic models and parameters. Methods and approaches for assessing the dermal exposure contribution relative to the biomarker measurements are of particular importance because dermal exposure methods are not well developed. Measured biomarkers will be related to potential exposure using algorithms used to estimate aggregate human exposure.
Goal/Objective:	To identify and evaluate environmental and questionnaire determinants of dose and to better understand the time course associations between exposure and dose. The dermal contribution to exposure will be analyzed.
Rationale for Project:	Study results will aid in the interpretation of exposure biomarker measurements and will help in the efficient design of future exposure and epidemiologic studies. Further understanding in the interpretation of biomarker levels is valuable because they are believed to provide a better predictor of health outcome than environmental concentration measurements that do not account for contact, uptake/intake, and absorption processes.
Suggested Approach:	Biomarker measurements represent the absorption and clearance of chemical contaminants measured in the NHEXAS program. The predictive relationship between these measurements will be evaluated with questionnaire responses, and with exposure and environmental media concentrations using multivariate analysis methods. Pharmacokinetic models will be applied in order to explain the relationship between exposure and dose (biomarker) measurements. Contributions of contaminated media can be estimated using exposure algorithms routinely used in exposure assessment.
Data or Input Needs:	Chemical measurements in biological, exposure, and environmental media, questionnaire data, exposure factors, and pharmacokinetic parameters.
Feasibility (of analyses with current NHEXAS databases):	Sufficient detectable results are needed in media of exposure relevance for biomarker analytes. Need to consider timing of biomarker collection relative to exposure and environmental measurements (e.g., Maryland study samples collected at beginning of sampling), and the availability and suitability of available pharmacokinetic parameters for the subpopulations (e.g., children).

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Multivariate statistical analyses; evaluation of short-term clearance models
	Month	24	(3) Final outputs: Journal article identifying predictors of dose
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	25	24	Principal investigator
			Senior-level staff ("associate")

	100	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Associations/Models of Internal Dose.

Project Name:	**EA-11. Critical Exposure Pathway Analysis and Comparison of Findings Among NHEXAS Studies**
Short Project Description:	This study will compare the results of analyses (or models) developed by each of the NHEXAS studies that apportion the relative contributions of environmental media and routes of exposure to "total exposure" or dose.
Goal/Objective:	To compare the approaches, data, and estimates used to apportion pathway-specific exposures used in the NHEXAS studies—identify similarities and differences and compare or pool results where possible.
Significance of Project:	Determine how the results (parameter estimates) from the individual NHEXAS studies can be systematically compared to each other, or pooled to provide combined estimates of associations between pathway-specific measurements/estimates and "total" exposure or dose.
Suggested Approach:	For each study, examine the sampling and analytical methods to determine if the resulting measurements are similar or different. Construct exposure distributions for each media. Compile estimates for associations of media concentrations and route-specific exposures (or surrogates) with "total" exposure or absorbed dose estimates from each study. Compare results (parameters and error terms) among individual studies. Pool data where measurements are similar to make generalized statements about exposure if reasonable.
Data or Input Needs:	Summary information about sampling and analytical methods. Individual study results for analyses of pathway-specific contribution to total exposure or dose.
Feasibility (of analyses with current NHEXAS databases):	Information (publications) and data should be readily available. Analyses may be limited by nondetectable or missing measurements.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Individual distributions of exposure data, pooled data sets, and comparative analyses
	Month	18	(3) Final outputs: Report on the similarities and differences of NHEXAS data and an assessment of linkages of activities to pathways
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**

	25	18	Principal investigator
	25	18	Senior-level staff (“associate”) statistician
	50	18	Junior-level staff (“assistant”, technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Methods.

Project Name:	**EA-12. Cumulative Exposures to NHEXAS Chemicals Having Similar Health Endpoints and Possible Additive or Synergistic Effects**
Short Project Description:	This project will calculate a toxic-equivalency weighted index of population "cumulative" exposures for suites of chemicals that are associated with common health endpoints and the exposure measurements from the NHEXAS studies. The NHEXAS target chemicals will be reviewed, using existing toxicological or epidemiological literature, to identify suites of chemicals having similar health endpoints (risks) and possible additive or synergistic effects. Possible health endpoints include neurological, reproductive/developmental, cancer, and immunological effects. Chemical classes include metals, VOCs, pesticides, and PAHs.
Goal/Objective:	To assess cumulative exposure to multiple chemicals of similar action/toxicity.
Significance of Project:	The Food Quality Protection Act calls for assessment of cumulative risk to pesticides (and toxic substances) having common endpoints and mechanisms of effect. This project will allow calculation of cumulative exposure indexes and their distributions, based on exposures to more than one chemical.
Suggested Approach:	(1) Using common health effects and additive or synergistic endpoints, and toxic equivalency or potency factors. (2) Examine the target chemicals and data from NHEXAS to identify chemicals that could be combined to provide a common exposure metric. (3) Calculate a weighted index of "cumulative" exposure using the absorbed dose estimated from the NHEXAS study data.
Data or Input Needs:	Data on selected chemical exposures and biomarkers from the three NHEXAS studies. Toxicological information on chemicals with common health endpoints and mechanisms and potency estimates (or toxic equivalency factors). Epidemiological information on possible additive or synergistic effects.
Feasibility (of analyses with current NHEXAS databases):	Toxicological data on potency should be readily available; information on "cumulative" risks (common endpoint and mechanism of action) may be limited to certain classes of chemicals (e.g., pesticides). The NHEXAS data may be limited in providing measurements in all exposure media for contaminants and classes.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Collect toxicology data on NHEXAS chemicals
	Month	9	(3) Obtain NHEXAS measurement data for selected chemicals
	Month	12	(4) Calculated exposure index for NHEXAS pesticides
	Month	18	(5) Calculated exposure index for metals
	Month	24	(6) Calculated exposure index for VOCs
Approximate Level of Effort:	% Time	Month s	**Type of Expertise Needed**
	20	24	Principal investigator
	50	6	Senior-level staff ("associate")
	50	24	Junior-level staff ("assistant", technician), students

			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES:
Classification: Associations/Models of Exposure.

4.4 LESSONS LEARNED GROUP

The lessons learned breakout group will focus on analyses that identify study elements that will be generally useful in the future or that will require modification or deletion in follow-up research. This includes, for example, a description of the achievement of data quality objectives; a description of response rates and survey design effects; the ability of the questionnaire and environmental and biological data to predict exposure and dose; a comparison of sampling and analytical methods; and the efficacy of communication with states and communities and local and public health departments.

4.4.1 SAB Comments

(1) "The EPA should use the experience, lessons learned, and wisdom gained from the pilot studies to guide the Agency and external investigators on how to optimize the measurement and analytical approaches." [3.4.2, 4][3]

(2) "Another important issue to address is the amount and nature of the new knowledge derived from the pilot studies as it relates to the methodologies implemented." [3.4.1]

(3) "The Committee recommends that the EPA use the data from the NHEXAS pilot studies to build the premises for a national exposure survey. Planning for Phase 2, a national surveillance plan, should require a plan that uses the experience of the pilot study so that the most appropriate multimedia measurements (including questionnaires) are used in Phase 2." [3.5.2.e]

4.4.2 Questions To Address

[3]Numbers in brackets are cross-references to sections in the SAB report.

As a starting point to identify, describe, and prioritize potential projects, the breakout group should consider the following questions and determine what additional critical questions should be added.

(1) What are the critical "lessons-learned" questions associated with

   (a) Aspects of *overall program management* including planning and conducting the study, and documenting and reporting the results?

   (b) Representativeness of *survey designs* and effects related to probability sampling, sample size and weighting, stratification and oversampling, and demographics?

   (c) Recruiting participants and the possible impact of different procedures and incentives on response rates?

   (d) Effectiveness and limitations of *study designs* for estimating multimedia, multipathway exposures for the general population, for susceptible subpopulations, and for the highest exposed?

   (e) Use of *field monitoring procedures* (e.g., questionnaires, sampling methods, sample handling and tracking), their burden on participant, practicality of application, and costs versus benefits?

   (f) Effectiveness of questionnaires/diaries in collecting information to estimate or describe exposures (e.g., burden, cooperation, compliance utility)?

   (g) Limitations associated with *sample analysis*—in selecting analytes; attaining appropriate detection limits and QC; and holding, shipping, and storing samples?

   (h) Creating and archiving *databases*?

   (i) Communicating data to participants, state and local health agencies, and the scientific community?

(2) What are the most critical QA/QC analyses that must be conducted?

(3) How are relative costs of each component of the study evaluated? How are the costs of one approach evaluated relative to another?

(4) What analysis approaches can be used to predict exposure and dose from questionnaires and environmental and biological data? How are these approaches evaluated?

4.4.3 Discussion Considerations

(1) What statistical analysis can be conducted with the information obtained in the demonstration studies to answer each of these questions? Which are feasible?

(2) Are there other approaches to answering each of these questions?

(3) What analyses can be conducted to evaluate the limitations of the studies?

(4) What analyses can be conducted to develop an efficient design for future studies—to measure central tendencies, to measure high upper percentiles of the exposure distribution, to identify distributions for susceptible subpopulations?

4.4.4 Brainstorming List of Projects

The following is an unranked listing of the lessons learned project titles proposed by the Lessons Learned Breakout Group as a result of the brainstorming sessions held on July 27 and 28, 1999. The projects are listed below each of the questions they address, in accordance with the organization and format of the brainstorming sessions. Question 10 incorporates additional questions and projects considered by the group. Following the brainstorming session, the group combined this list into 14 project areas, of which 13 were further developed into the project descriptions in Section 4.4.5 (the 14th was passed to the Exposure Assessment Group for consideration). None of the project areas was eliminated from consideration. The numbers in parentheses following the projects are cross-referenced to the project descriptions in Section 4.4.5.

1. *Aspects of program management, including planning and conducting the study and documenting and reporting the results?*

   (1) Document what has been learned to build for the future. (LL-3)

   (2) Survey start-up costs associated with NHEXAS, with the goal of minimizing costs by and across consortia:

   - infrastructure costs,
   - identify cost efficiencies in conducting NHEXAS projects. (LL-11)

   (3) EPA should analyze coordination and communication within and across agencies, and across consortia. (LL-11)

(4) What is impact of nonuniformity of methods and procedures across the consortia? (LL-10, LL-11)

(5) Identify and evaluate appropriate QA/QC across laboratories and data reporting formats; include NIST evaluation and optimize for future studies. (LL-10)

2. *Representativeness of survey designs and effects related to probability sampling, sample size and weighting, stratification, oversampling, and demographics?*

(1) Analyze the data for variance components, including spatial, time, population and subpopulation, activities by different pathways, and different pollutants for impact on future NHEXAS survey designs. (LL-2)

(2) Analyze the NHEXAS-generated data to address the quality of assumptions about the design effects and variables as presented in the paper by Callahan et al., 1995. (LL-1)

3. *Recruiting participants and the possible impact of different procedures and incentives on response rates?*

(1) Analyze data to compare strategies and recommendations for recruitment, impact on response rates, and incentives (utilize NHEXAS and data from other studies)—a retrospective look at successes and failures. (LL-5)

(2) Identify key factors associated with recruitment and response rates. (LL-5)

(3) Analyze nonresponse bias for the population and various subgroups across consortia. (LL-5)

4. *Effectiveness and limitations of study designs for estimating multimedia, multipathway exposures for the general population, for susceptible subpopulations, and for the most exposed?*

(1) Similar to analyses proposed to address question 2 and also to include analysis of participant and field team burden. (LL-7)

(2) Summarize experiences related to use of screening tools for future study by chemical and media. (LL-6)

(3) Analyze data to address strategies for designing NHEXAS studies related to time intervals of concern and limits of detection and method sensitivity. (LL-6)

(4) Compile data and experiences across consortia to optimize future studies across media, pathways, pollutants, and pollutant classes. (LL-3)

5. *Use of field monitoring procedures (e.g., questionnaires, sampling methods, sample handling and tracking), their burden on participant, practicality of application, and costs versus benefits?*

   (1) Document field monitoring logistics, including procedures (and recommendations for improvement), shipping, sample preservation, etc. (LL-7)

   (2) Document successes and failures. (LL-7)

   (3) Evaluate monitoring procedures across consortia, against various criteria, such as burden, costs, accuracy and precision, sensitivity, relevancy to study objectives, etc. (LL-7)

6. *Effectiveness of questionnaires and diaries in collecting information to estimate or describe exposures (e.g., burden, cooperation, compliance utility)?*

   (1) Compliance issues. (LL-12)

   (2) Consistencies of response. (LL-12)

   (3) Reliability and validity. (LL-12)

   (4) Indicators of exposure (referred to the Exposure Assessment Group).

   (5) Relate the questionnaire rationale used in the Office of Management and Budget (OMB) approval with actual responses. (LL-12)

   (6) Evaluate the effectiveness of dietary check-off list with food diary. (LL-12)

   (7) Time/activity pattern and video analysis with comparisons to exposure (referred to the Exposure Assessment Group).

7. *Limitations associated with sample analysis, selecting analytes, attaining appropriate detection limits and QC, and holding, shipping, and storing samples?*

   (1) Provide an interpretive report of the comparability experiment across consortia, including an analysis of data quality. (LL-10)

   (2) Evaluate methods across media (equivalency, etc.). (LL-7)

8. *Creating and archiving databases?*

   (1) Document *limitations* of NHEXAS data. (LL-13)

(2) Standardize ways to document data across consortia. (LL-13)

(3) Creation and standardization of an information shell that includes field collection observations and issues. (LL-13)

(4) Assessment of the processes used by each consortium. (LL-13)

(5) QC data and coordination with EPA data quality indicator project. (LL-13)

9. *Communicating data to participants, state and local health agencies, and the scientific community?*

(1) Develop a uniform strategy for future studies that is consistent with human subjects Institutional Review Board review requirements and participant confidentiality issues. (LL-7)

(2) Participant interpretation issues—develop a plan for the future through interviews with NHEXAS researchers. (LL-7)

10. *Other questions and projects proposed by the group:*

(1) Time integration issues: acute verses long-term exposures. (LL-2)

(2) Analysis of variance (population versus individual). (LL-2)

(3) Value of information and cost benefit of

- questionnaires,
- biomarkers,
- environmental concentration, and
- personal exposures. (LL-8)

(4) Identify clusters, factors, and principal components associated with population distributions resulting from NHEXAS. (LL-2)

(5) What have we learned and what do we still need to know? (LL-4)

(6) How can pilot information be analyzed to design the optimum national NHEXAS survey? (LL-4)

(7) Define methods to optimize exposure management and reduction and the effectiveness of regulations. (LL-4)

(8) Identify differences between NHEXAS and NHANES. (LL-4)

(9) Evaluate hypotheses; what was testable, why or why not? (LL-1)

4.4.5 Project Descriptions

Project Name:	**LL-1. Survey and Statistical Aspects of the Design of an Exposure Field Study: Lessons Learned from the NHEXAS Pilot Studies**
Short Project Description:	This project is a review, revision, and updating of the discussions, analyses, and conclusions in the Callahan et al. paper (JEAEE, 1995) in light of the NHEXAS experience. The hypothetical calculations in Callahan would be replaced with calculations based on actual NHEXAS data. In addition, the analytical and statistical hypotheses that were generated in the design of the NHEXAS pilots will be reviewed to determine which hypotheses were testable and which were not.
Goal/Objective:	The objective of the project is to provide directly relevant and specific guidance for the sample and survey design aspects of a national NHEXAS or other large multichemical, multimedia exposure field study.
Significance of Project:	The Callahan paper influenced the design of the NHEXAS pilots. Its revision will provide scientifically relevant, specific, and current guidance for the design of a full national NHEXAS, and also for other regional or national human exposure field studies, especially multichemical, multimedia studies.
Suggested Approach:	Callahan et al. (JEAEE, 1995) discussed the statistical and survey design issues involved in designing a population-based environmental exposure study. It made a number of design recommendations – about the optimal selection of Primary and Secondary Sampling Units (PSUs and SSUs) and households, about screening strategies, about the selection of target household member, etc. Many of these recommendations were based on calculations of hypothetical intraclass correlations, design effects, and variances. There is now a wealth of data available from the three NHEXAS pilot studies that is germane to these survey design issues. This project would involve a review of the discussions, analyses, and conclusions in Callahan in light of the NHEXAS experience. The hypothetical calculations of design effects and intraclass correlations would be replaced with calculations based on actual data, and the conclusions and recommendations revisited. These analyses would be repeated for different pollutants and classes of pollutants to determine if different conclusions would be reached for different pollutants. In addition, the analytical and statistical hypotheses that were generated in the design of the NHEXAS pilots will be reviewed to determine which hypotheses were testable and which were not. Testability would be measured through the calculation of the statistical powers of the tests. Tests with high powers would be deemed testable, whereas tests with low power would be deemed not testable. Through a review of the data, the reasons for the ultimately testability will be determined. These calculations will lead to conclusions regarding the testability of the hypotheses, and the optimal design of future environmental exposure studies.
Data or Input Needs:	For each household in each of the three NHEXAS pilots, the following data are needed: the PSU and SSU containing the household; the design stratum containing the household; and the data on each pollutant/medium sampled.
Feasibility (of analyses with current NHEXAS databases):	The current NHEXAS data files have the necessary data to perform the calculations. At worst, there are potentially small or empty cells in the survey designs that might force combining cells or qualifying the conclusions.

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project
	Month	1-3	(2) Gather data sets; plan, review, and approve the statistical analyses
	Month	4-8	(3) Perform the statistical analyses
	Month	9	(4) Draft the report
	Month	9-12	(5) Review, revise, and finalize the report

	Month	12	(6) Final output: Report with recomendations for the optimal design of a national-scale human exposure study
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed** Senior and mid-level survey statisticians, systems analysts, programmers
	25	12	Principal investigator
	50	9	Senior-level staff ("associate"), senior survey statistician, database manager/programmer, data analyst
	100	6	Junior-level staff ("assistant", technician) students, mid-level survey statistician, programmers

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-2. Characterization of the Variance Components of NHEXAS Data to Optimize Future Designs**
Short Project Description:	Characterize the variance components of NHEXAS data, including the inter- and intrapersonal, temporal (e.g., integration time, seasonal, weekly), activity-related, and spatial variabilities by sample size for each of the pollutants by pathway/medium and by integrated total exposure. Results will be used to optimize future NHEXAS design.
Goal/Objective:	The primary goal of the proposed project is to use the NHEXAS data to determine the appropriate sampling strategies for the different pollutants and pathways. To achieve this goal, the proposed project will characterize the variance components of the NHEXAS exposure data to • estimate the optimum sample size and number of repeated measures (SAB comments II.A.2 and 4); • determine how exposure distributions vary across time and space and identify factors that influence this variation (II.A.2); • assess whether the variance components differ by subpopulation, including susceptible and highly exposed subpopulations (II.A.4); and • investigate how the exposure characteristics of the various subpopulations are influenced by activity patterns, geographic area, and SES (II.A.4).
Significance of Project:	The proposed project directly addresses SAB concerns and, as a result, will improve substantially the ability to optimize the design of future NHEXAS and other exposure studies. It will incorporate findings from each of the three NHEXAS consortia and will allow the sampling plan of each consortium to be examined in a systematic and quantitative manner.
Suggested Approach:	Exposure data from each of the three NHEXAS studies will be analyzed to determine the inter- and intrapersonal, temporal, and spatial variabilities in exposure distributions. Analysis will be performed by pollutant, both pathway-specific and as integrated total exposure, as well as by subpopulation. Variabilities will be assessed using standard statistical approaches, including the coefficient of variation and one-way analysis of variance (ANOVA) and mixed model approaches. Graphical techniques will be used to evaluate and determine appropriate pollutant- and media-specific sampling strategies. As possible, pollutants will be grouped based on identified appropriate sampling strategies.
Data or Input Needs:	From each pilot study (and primarily the Maryland NHEXAS study for temporal data), the following data will be needed: • environmental concentration and exposure data, • questionnaire data, and • time/activity data.

Feasibility (of analyses with current NHEXAS databases):	High, all the necessary data exists.		

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: Compilation of the data from the consortia
	Month	3-18	(2) Analyses of the data
	Month	15-24	(3) Final outputs: • Reporting of the optimized sampling strategies by pollutant and pathway • Publishing in peer reviewed journals
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	24	Principal investigator
	100	24	Senior-level staff ("associate")
	100	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-3. Using Lessons Learned To Move to a National NHEXAS or Other Major Field Study**
Short Project Description:	This project will capture and integrate the knowledge gleaned from the analysis, interpretation, and evaluation of the experiences in undertaking the NHEXAS pilot studies for assisting in designing and planning the next generation of NHEXAS or other major field studies. Included would be an evaluation of the ability of each consortium to achieve the objectives or hypotheses originally proposed for each type of investigation.
Goal/Objective:	(1) To compile the results and conclusions from the analyses conducted by the NHEXAS studies. (2) To evaluate the successes and failures of the individual pilot studies in achieving the original hypotheses proposed by each consortium. (3) To document the successes and shortcomings of the NHEXAS pilot studies based on the outcomes of implementing the entire strategic analysis plan. (4) To synthesize a strategy to begin the process of designing the next generation of NHEXAS based on the successes and shortcomings from the evaluation of the NHEXAS pilot studies.
Significance of Project:	The products and outcome of this effort are needed to provide justification and a defensible scientific basis to begin designing a national-scale NHEXAS.

Suggested Approach:	(1) Obtain completed significant analyses on the databases and information content obtained by each consortium, and from the implementation of the Strategic Analysis Plan. (2) Develop a plan to utilize a multidisciplinary team to undertake and complete Goals/Objectives 1 through 3 for this project. (3) On completion of Goals/Objectives 1 through 3, Goal/Objective 4 will be implemented by EPA.
Data or Input Needs:	The analyses conducted to achieve each study's hypotheses and objectives and the results from the implementation of the SAB-approved Strategic Analysis Plan. The project initiation is contingent on having sufficiently completed products from other projects in the Strategic Analysis Plan.
Feasibility (of analyses with current NHEXAS databases):	High, if the Strategic Analysis Plan is implemented, including the lessons learned projects.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	1	(1) Initiate project:
	Month	2-4	(2) Collect and compile from other project
	Month	5-7	(3) Evaluate information and summarize findings
	Month	12	(4) Final outputs: Final report
Approximate Level of Effort:	% Time	Month s	**Type of Expertise Needed**
	50	6	Principal Investigator
	300	36	Senior-level staff ("associate")
	0	0	Junior-level staff ("assistant", technician), students
	100	12	Other (describe): Secretarial support

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL- 4. Optimizing NHEXAS Pilot Information and Methods To Achieve Exposure Management, Exposure Reduction, and Improved Effectiveness of Regulatory Strategies**
Short Project Description:	A thorough evaluation will be performed of single- and multimedia pollutant issues and regulatory initiatives for the purpose of designing the national scale NHEXAS. The information obtained in the pilot studies and other source and effects information will be utilized to prioritize the selection of pollutants and pathways leading to exposure.
Goal/Objective:	(1) To build a knowledge base on the current and emerging scientific and regulatory issues associated with pollutants and their occurrence in multimedia. (2) To build a knowledge base on the prevalence of xenobiotics measured in biological samples from human populations. (3) To develop strategies for optimizing exposure information that permit effective management and reduction programs. (4) To link the accomplishments of objectives 1 through 3 to support moving forward, as part of the input to the design of the national-scale NHEXAS.
Significance of Project:	This project provides scientific and policy buy-in for justifying the implementation of a national-scale NHEXAS.
Suggested Approach:	The implementation of this project is an EPA initiative. It requires NERL to identify a team of scientists to work with the program offices, other government agencies, states, and other stakeholders to acquire the knowledge base for selecting and prioritizing pollutants and pathways and for identifying innovative exposure reduction strategies. Evaluate the success and completeness of the above in workshops composed of EPA and extramural scientists, other professionals, and stakeholders. Incorporate the output from the workshops to refine and augment the knowledge base to be used for designing the national-scale NHEXAS. The knowledge building should begin as soon as practical and be completed in a timely fashion to be ready to support moving to the future NHEXAS.
Data or Input Needs:	Information is obtained from the NHEXAS Strategic Analysis Plan results, program office activities and initiatives, NHANES, other exposure and health-related studies (e.g., EPA/ORD STAR Grant Program, NIEHS, National Cancer Institute, Health Effects Institute, National Institute for Occupational Safety and Health, ATSDR), and state exposure data and pollution reduction initiatives.
Feasibility (of analyses with current NHEXAS databases):	High, if initiated in a timely manner.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	1-4	(2) Building a knowledge base
	Month	5-7	(3) Identifying strategies and conducting a workshop
	Month	8-9	(4) Final outputs: Synthesis of information and transferring output to support moving to the future NHEXAS
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	100	9	Principal investigator

	200	18	Senior-level staff (“associate”)
	50	4.5	Junior-level staff (“assistant”, technician), students
	100	9	Other (describe): Secretarial and other support staff
			Cost of workshop

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-5. Influence of Incentives, Response Rates, and Nonresponse Bias on Survey Design**
Short Project Description:	Analysis of NHEXAS recruitment procedures and incentives and their effects on response rates for various subpopulations. Analysis of potential bias resulting from NHEXAS nonresponse based on information obtained from the Descriptive Questionnaire, and information/observations recorded by interviewers on noncontacts or nonrespondents for each study and for various subpopulations.
Goal/Objective:	Determine the recruitment procedures and incentives that should be recommended for a national NHEXAS or other large field study. Determine the extent of nonresponse bias that can be expected at each stage of these studies.
Significance of Project:	Projected participant incentives and response rates will be a major consideration for OMB approval of a national NHEXAS. It will be necessary to project reasonably high response rates and to justify the incentives and procedures proposed to achieve those response rates.
Suggested Approach:	Contrast recruitment strategies, information provided to potential respondents, incentives, and response rates across (and within, where feasible) the three NHEXAS pilot studies for subpopulations of interest. Compare NHEXAS recruitment procedures, incentives, and response rates with those from other studies collecting comparable data (e.g., TEAM and NHANES). Use the NHEXAS Descriptive Questionnaire data to compare characteristics or respondents and nonrespondents • for each NHEXAS pilot study, • for each stage of participation, and • for subpopulations of interest (e.g., race/ethnicity; gender; urbanicity).
Data or Input Needs:	Indicators from each NHEXAS pilot study of participation for each stage of the study: Households contacted (no answer/refusals/number of contacts) Descriptive Questionnaire Baseline Questionnaire Core monitoring Sampling for each matrix and pollutant Documentation of the recruitment procedures (including information provided, informed consent, approaches used for questionnaires and sampling, communications and contacts with press/community, etc.) and incentives used by each NHEXAS pilot study NHEXAS Descriptive Questionnaire data Incentives, recruitment procedures, and response rates for other studies collecting comparable data (e.g., TEAM and NHANES) Quality Systems Implementation Plans, protocols for survey sampling and training manuals for survey teams

Feasibility (of analyses with current NHEXAS databases):	Must complete QC on Descriptive Questionnaire data for each NHEXAS consortium. Must complete NHEXAS chemical analyses, set respondent flags, and QC those flags. Must document all NHEXAS respondent selection procedures for each stage of each study.

Project Name:	LL-5 (cont'd). Influence of Incentives, Response Rates, and Nonresponse Bias on Survey Design		

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project
	Month	6	(2) Secure necessary data; QA data
	Month	12	(3) Final outputs: Impact of response rates on survey design
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	12	Principal Investigator
	50	12	Senior-level staff ("associate")
	50	12	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-6. Application of Screening Tools for Large-Scale Exposure Field Studies**
Short Project Description:	Analyze data from NHEXAS pilot studies to assess the reproducibility, accuracy (i.e., false positive/false negative), limits of detection (LODs), ranges, interferences, and costs of screening methods relative to data obtained. From the analysis, identify methods that were unsuccessful and other methods (i.e., questionnaires) that could serve as screening tools in large-scale exposure studies to identify more highly exposed individuals and reduce costs.
Goal/Objective:	To evaluate the utility of low-cost screening methods (1) for identifying households or subjects requiring more intensive monitoring and (2) for providing data useful for exposure assessment (e.g., distributions).
Significance of Project:	Multimedia, multipathway studies are expensive to implement. For some pollutants and media, a large proportion of the samples may have no detectable analytes. A study design may require identifying highly exposed individuals for intensive study. Screening methods are needed to provide a low-cost approach that can identify highly exposed individuals and which samples or media should be analyzed. In addition, screening methods with sufficient quantitative power may provide data adequate for exposure analysis. Assessment of screening methods and concentration data obtained from the pilot studies will provide valuable information to guide future NHEXAS studies.
Suggested Approach:	(1) Identify screening methods, or methods that could be used for screening, from the NHEXAS pilot studies. (2) Assess the ranges, reproducibility, accuracy (i.e., false positives/false negatives) and LODS for identified screening methods with more rigorous and expensive methods. (3) Evaluate questionnaire data as a screening tool. (4) Determine which methods were successful (or could be successful) and those that were not. (5) Assess the cost and burden (participant and field staff) of methods that show promise for use in future studies.
Data or Input Needs:	(1) A listing of field and analysis methods used by each NHEXAS pilot study consortium with the applicable analytes, LODS, range, and associated QC data. (2) Results for paired low-cost/high-cost methods at homes where two adults were employed. (3) Information about the time and effort needed to implement each field collection or measurement method and any associated laboratory and analysis costs.
Feasibility (of analyses with current NHEXAS databases):	There are sufficient data groups to allow the proposed analysis. Some examples include, for VOCs, photoionization detector and passive diffusion badges versus actively pumped sorbent tubes; for pesticides, immunoassay methods and analyses by gas chromatography with various detectors; for metals, XRF versus inductively coupled plasma (ICP) with various detectors, atomic emission spectrophotometry and ICP/MS; for PAHs in air, real-time PAH monitor.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	4	(2) Compile listings of methodology and associated data (QC, range, LOD) from databases
	Month	12	(3) Statistical comparisons of paired sample results, assessment of success and cost of potential screening methods

	Month	18	(4) Final outputs: Final report or manuscript describing screening method assessment results
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10%	18	Principal investigator
	25%	18	Senior-level staff ("associate")
	50%	6	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-7. Lessons Learned from Field Sampling and Laboratory Experience in the NHEXAS Pilot Studies**
Short Project Description:	Actual experiences of NHEXAS pilot study personnel will document important lessons learned from conducting field monitoring and laboratory analyses.
Goal/Objective:	Document field and laboratory procedures used in the NHEXAS pilot studies, identify procedures that worked well, and provide recommendations for improvement. Pilot study sampling and analysis outcomes will be compared with expected outcomes to assess their applicability and utility for future NHEXAS studies.
Significance of Project:	A great deal of the actual experience gained from the NHEXAS pilot studies has not been documented formally and would be invaluable in the design and implementation of a large-scale exposure study.
Suggested Approach:	(1) Develop interview questions/issues. (2) Interviews and/or a workshop for pilot study field and laboratory personnel. (3) Document procedures and practices not captured in standard operating procudures (SOPs) that are critical for efficient implementation of large-scale multimedia and multipathway studies. (4) Compare actual QC (accuracy, precision, and LODS) and data range results with expected results to assess the applicability of the procedures to large-scale exposure studies. (5) Evaluate process of administering questionnaires, sampling methods, sample handling and tracking, laboratory procedures, participant training and burden (time and level of understanding), field staff burden (time and training), etc.
Data or Input Needs:	(1) Interviews with NHEXAS pilot study personnel (consortium, federal agencies, and federal contract labs). Information collected from interviews will address procedures and practices, including the effectiveness of administering questionnaires, sampling methods, sample handling and tracking, laboratory procedures, participant training and burden (time and level of understanding), field staff burden (time and training), etc. (2) Quality control data and sample result ranges for each of the sampling/analysis methods used in the NHEXAS pilot study.
Feasibility (of analyses with current NHEXAS databases):	This project is currently feasible if initiated in a timely manner because most personnel associated with the NHEXAS pilot studies are available and able to recall anecdotal information. It will be important to implement the interviewing portion of this project as soon as possible to capture this information. The other data needed for this evaluation is available now, or will be available as the NHEXAS pilot study databases are completed.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Develop interview questions
	Month	6	(3) Implement interviews with NHEXAS personnel
	Month	6	(4) Assemble QC and sample result ranges
	Month	9	(5) Compare actual results with expected results
	Month	12	(6) Final outputs: Report documenting field monitoring and laboratory analysis experience and lessons learned. Report or manuscript comparing actual to expected QC and data range results

Approximate Level of Effort:	% Time	Months	Type of Expertise Needed
	5	12	Principal investigator
	20	12	Senior-level staff (“associate”)
	100	9	Junior-level staff (“assistant”, technician), students
			Other (describe): Visits to NHEXAS centers; travel needed

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-8. Value of Information and Cost-Benefit Analysis of Exposure Measures**
Short Project Description:	The proposed project will evaluate the cost-effectiveness of the various exposure measures for each of the pollutants and pathways using decision analysis, value of information, and cost-benefit analysis techniques. Specifically, the proposed project will compare the relative cost effectiveness of questionnaires, environmental sampling, personal sampling, and biomarkers to assess exposures to each of the pollutants. The proposed analyses will include exposure assessment methods used in the NHEXAS pilot studies, as well as assessment methods developed more recently.
Goal/Objective:	The primary objective of the proposed project is to compare the costs and benefits of methods used to characterize multimedia exposures for each pollutant and examine their implications on sample size needs, sampling costs and burdens to the study subjects.
Significance of Project:	The proposed project directly addresses SAB concerns (Comments A, B, and C) and, as a result, will improve substantially the ability to optimize the design of future NHEXAS and other exposure studies. Findings from each of the NHEXAS pilot studies will be used to design the most cost-efficient exposure data sampling strategy for the future NHEXAS.
Suggested Approach:	For each pollutant and pathway, the proposed study will: • identify the exposure assessment tools and methods (e.g., questionnaires, micro-environmental and personal sampling, biomarkers) used in each of the three studies and from other post-NHEXAS efforts; • estimate the associated costs, data quality, and sample size requirements for each method; • use value of information and cost-benefit analysis tools to determine the cost-effectiveness of each method; and • develop methods selection criteria.
Data or Input Needs:	From each NHEXAS study, the following will be needed: • concentration, biomarker, questionnaire, and time/activity data; • methods performance data; • the method-specific direct costs and other resource requirements; and • relevant data from recent method development studies.
Feasibility (of analyses with current NHEXAS databases):	High, all needed data exist.

Approximate Project Time Table and Level of Effort

Time Table:	Duration[*]	Research Outputs

	Month	0	(1) Initiate project: Data collection and compilation
	Month	3-12	(2) Data analyses
	Month	12-18	(3) Final outputs: Comparative analysis of different exposure assessment methodologies, methods selection criteria, and peer-reviewed publications
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	9	Principal investigator
	100	18	Senior-level staff ("associate")
	100	18	Junior-level staff ("assistant", technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-9. Assessments and Recommendations for Effective Communications**
Short Project Description:	The purpose of this project is to review the communications procedures put in place by each of the three NHEXAS pilot studies, as they shared individual results with respondents and composite data or other data with local, state, and federal officials and organizations.
Goal/Objective:	The goal of this project is to compare and contrast the participant communication strategies implemented by the three consortia and to determine which strategies or components worked well and which components need improvement.
Significance of Project:	Participant communication is a component of human exposure assessment that often is overlooked or given low priority by both project planners and sponsors, yet it is an important component of the overall package of benefits that are provided to the respondents and which serves as a significant component of the package of incentives used to promote participation. In addition, timely reporting of values that exceed nominal thresholds is a mandatory component of all human exposure research.
Suggested Approach:	• The processes used in the three pilot studies to share individual results with the respondents will be reviewed and compared. The respondent may be recontacted for a brief interview to determine how well the respondent understood the information that was provided and to determine what questions were not answered for the respondent. As part of the interview, or in a focus group setting, the same data information using each of the processes used in the three studies will be shared. This will allow direct comparison of varying approaches and should determine the best means of sharing data in this setting. • Next, interviews with the local and state agencies that received notification from any of the three studies for measured values exceeding state or local reporting thresholds will be held. The process by which the data were shared, what each agency did after receiving the data, and the range of thresholds reported by the states will be reviewed. Threshold values used at the local, state, and federal level will be compiled. • Then, the reporting mechanisms in place for the three studies will be reviewed for common approaches. A sample of the recipients of the reports will be selected and interviews or focus groups will be conducted to assess the utility of the reports and will seek to determine the information missing from the reports or the information that was provided in a manner that minimized its utility. Attempts will be made to determine what means of data reporting are of value to different levels of users, and to develop a basic format to be used in reporting composite data to subjects. • Finally, meetings will be held with state and local government agencies to review their role in release of data and dissemination of results. The ultimate product of these efforts would be a communication evaluation manual.
Data or Input Needs:	Copies of material used by each of the consortia to provide results to the respondents. Copies of reports providing composite data to local, state, and federal agencies that provided support or assistance during the survey design phase or during data collection
Feasibility (of analyses with current NHEXAS databases):	No database access is required. This effort will require access only to copies of material used by the consortia to share information with respondents and to the reports used to provide composite data. Therefore, this project is feasible without access to current or future databases. Recontacting participants and state and local representatives may be problematic.

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project
	Month	6	(2) Compare NHEXAS processes
	Month	9	(3) Complete local/state interviews

	Month	12	(4) Final outputs: Document: Evaluation of approaches for effective communication
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	25	12	Principal investigator
	40	12	Senior-level staff (“associate”)
	50	12	Junior-level staff (“assistant”, technician), students
	25	12	Other (describe): Secretary

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-10. Evaluation of NHEXAS Results To Derive an Optimal Set of QA/QC Activities for Human Exposure Field Studies**
Short Project Description:	This project will identify and evaluate the QA/QC across laboratories and consortia. This will include an analysis of the NIST and comparability study data. The project will develop an annotated inventory of recommended QA/QC activities needed to successfully conduct large-scale human exposure measurement studies. This will include all phases of the study from planning to final database development.
Goal/Objective:	The goal of this project is to provide an optimum set of QA/QC activities for future human exposure studies. This is needed to assure that the studies produce data of the required quality while keeping costs to a minimum.
Significance of Project:	Effective QA/QC is essential to produce high-quality data from the funds invested in any field exposure study. Because of the high cost of these types of studies, it is also important not to include unnecessary QA/QC that might increase costs. By examining the QA/QC used in the NHEXAS studies, guidance can be developed for this critical study component.
Suggested Approach:	(1) Identify the QA/QC activities performed by each consortium and laboratory, including the NIST standards and performance evaluations studies, the interlaboratory comparability study, QA documentation, reviews, audit reports, reviews of field performance, and QA samples. (2) Evaluate the success of each activity and the benefits it provided to the study. (3) Identify areas where data quality could have been improved with additional QA/QC activities or areas where excess QA/QC activities might have been employed. (4) Develop an annotated inventory of the recommended QA/QC activities needed to conduct a large-scale human exposure study.
Data or Input Needs:	Access is needed to the complete sets of data and documentation, including all QA/QC information of each consortium and laboratory and the NIST and comparability study results and reports.
Feasibility (of analyses with current NHEXAS databases):	The study is feasible given access to the data from all studies. A mixture of laboratory, field and QA expertise is needed to evaluate information.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Review consortia documents

	Month	18	(3) Final outputs: • Consolidate information from documents and develop annotated inventory • Guidance document on optimal QA/QC for human exposure field studies
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	18	Principal investigator
	100	18	Senior-level staff (“associate”)
	200	18	Junior-level staff (“assistant”, technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-11. Effectiveness of Questionnaires/Diaries, in Collecting Information To Estimate or Describe Exposures for Determinants of Exposure**
Short Project Description:	The NHEXAS pilot studies utilized questionnaires for various determinants of exposure. This project will analyze the questionnaire data obtained from the three NHEXAS pilot studies for understanding the following aspects of exposure: compliance issues, consistencies of response, reliability and validity of questions, effectiveness of dietary questionnaires/check lists, and relationship of questionnaire rationale with response. This analysis will provide information needed to design better questionnaires/diaries for the national-scale NHEXAS.
Goal/Objective:	Determine the value of questionnaires for understanding various aspects of exposure and the reliability and validity of the instrument for ascertaining these factors. This analysis will influence the design and expected participant burden costs associated with future NHEXAS or similar exposure studies.
Significance of Project:	The relative value of questionnaires and diaries for understanding public health and exposure, as well as the item-by-item value of asking each question, will be determined with the overall goal of minimizing participant burden and costs.
Suggested Approach:	Each study utilized the same OMB-cleared questionnaire and activity diary instruments. The proposed analysis will evaluate the information content obtained from the questionnaires, the lessons learned from the administration and compliance issues, and other attributes to estimate their relative value. This will involve some comparison with exposure and environmental measurements to determine the value of the questionnaire item.
Data or Input Needs:	Databases, questionnaire information, and field observational data from each pilot study. Monitor sensor data to evaluate activity pattern diaries (NHEXAS Region V study only).
Feasibility (of analyses with current NHEXAS databases):	This analysis should be straightforward.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Obtain needed data
	Month	12	(3) Final outputs: Guidance document on formulating effective questions for future exposure studies
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	12	Principal investigator
	50	12	Senior-level staff ("associate")
	50	12	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-12. Scaling Up: Evaluation of the NHEXAS Pilot Fixed-Costs, Coordination and Degree of Standardization**
Short Project Description:	This project will evaluate the NHEXAS pilot start-up expenditures and cost implications for various scales of coverage. The evaluation also will address the effectiveness of coordination/communication approaches that were used and their application to a full scale survey. A key component of the analysis will be the evaluation of approaches that were standardized explicitly and a determination of whether or not the degree of standardization was adequate.
Goal/Objective:	To transfer the experience of the pilot to develop the most cost-effective full survey possible.
Significance of Project:	A full-scale survey will provide the data necessary to evaluate status and trends of human exposures on a national scale. Using empirical data from the pilot ensures that the most cost-effective approaches are used.
Suggested Approach:	(1) Interviews will be conducted addressing coordination, communication, and degree of standardization of management and staff from the involved agencies and consortia. (2) Collect cost information. (3) Review pilot documentation to determine where standardization occurred. (4) Review NHEXAS database. (5) Formulate recommendations for an optimum scale-up strategy.
Data or Input Needs:	Cost data; available documentation; NHEXAS database.
Feasibility (of analyses with current NHEXAS databases):	Highly feasible; all information ultimately available.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Collect needed data
	Month	12	(3) Final outputs: Report recommending optimum scale-up strategy
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	12	Principal investigator
	33	12	Senior-level staff ("associate")
	100	12	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**LL-13. Cross-Studies Evaluation and Recommendations for Standardization of Data Management Procedures in a National NHEXAS or Other Large-Exposure Field Study**
Short Project Description:	This project will analyze the data collection and automated survey management procedures developed for each NHEXAS pilot study from sampling, through sample analysis and to inclusion in the final database. The data QA/QC procedures will be evaluated, and the resulting database structures will be examined. The strengths and weaknesses of the three approaches will be noted with respect to ongoing EPA data management initiatives. NHEXAS pilot QC data will be analyzed, and recommendations for current and future studies will be developed. These recommendations will include areas that would benefit from standardization; for example, data transfer from analytical laboratories, database elements, QA/QC codes, information shells, etc.
Goal/Objective:	To have appropriate conventions and procedures for recording data and data quality and to increase the efficiency of future data collection efforts.
Significance of Project:	Management of large EPA databases as a valued resource is currently a high priority within EPA. Procedures and conventions used to manage the integrity of data are evolving but are essential to both primary and secondary data users. The NHEXAS studies are an excellent opportunity to analyze the procedures used by three different organizations to develop and populate study databases. Results of this project will be used for improving/optimizing data collection and storage for future human exposure studies and other EPA primary data collection efforts.
Suggested Approach:	(1) Assess the data management processes and conventions used in each NHEXAS pilot study. (2) Review the status of EPA efforts with respect to Reinventing Environmental Information (REI), specifically current status of data standards (Chemical ID, Location ID, etc.), the Environmental Data Registry (EDR), the Environmental Information Management System (EIMS) and any other relevant efforts to insure the quality and accessability of EPA databases. (3) With stakeholder input (EPA program offices, involved Federal agencies, etc.), recommend application of EPA conventions and procedures for a future national-scale NHEXAS or other large exposure field database. Recommend conventions in areas where none exist. Conventions that document the limitations of the data are particularly important. (4) Analyze available quality control information (i.e., batch level laboratory QC information) and develop Data Quality Indicators that can be stored with the data for the benefit of secondary data users.
Data or Input Needs:	Needed information includes the following for each consortium: data management plan/procedures; field data collection procedures; procedures for transferring the field, analytical, questionnaire/diary and related data into the final databases; data QA/QC procedures; and final database design. Each consortium also will need to provide an analysis of how well their procedures worked and problems encountered.
Feasibility (of analyses with current NHEXAS databases):	Data collection and processing SOPs are available from each consortium. The analysis of how well the procedures worked in each consortium will need to be done in the relatively near future, while the staff involved are still available. EPA-level initiatives in this area are active and ongoing.

Project Name:	**LL-13 (cont'd). Cross-Studies Evaluation and Recommendations for Standardization of Data Management Procedures in a National NHEXAS or Other Large-Exposure Field Study**		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Collect and review NHEXAS SOPs and QA documentation
	Month	12	(3) Final outputs: A data management strategic plan for future exposure field studies
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	12	Principal investigator
	50	12	Senior-level staff ("associate")
	50	12	Junior-level staff ("assistant", technician), Students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

4.5 MODELING GROUP

The charge to the modeling breakout group is to consider a number of multimedia and multipathway exposure and dose modeling approaches that can be implemented with the NHEXAS data collected. Specifically, the group is asked to recommend a number of robust modeling strategies for estimating pathway-specific and aggregate exposures and dose from a variety of NHEXAS pollutants. The participants also will suggest investigations designed to calibrate, test, and evaluate multimedia and multipathway models using the NHEXAS concentration exposure and biomarker data.

4.5.1 SAB Comments

In its review of the NHEXAS pilot study, the SAB recommended conducting modeling studies with the NHEXAS data. Specific comments include the following.

(1) Develop physical models that integrate exposures from different media in order to estimate long-term exposures from short-term measurements [3.2, 3.2.2.d, 3.2.2.g].[4]

(2) Develop models for identifying factors related to high-end exposures [3.2.2.g].

(3) Address model validation and refinement [3.2.2.a, 3.2.2.g].

(4) Apply NHEXAS data to ongoing modeling projects such as TRIM and CEM [3.2.2.g].

4.5.2 Questions To Address

As a starting point to identify, describe, and prioritize potential projects, the breakout group should consider the following questions and determine what additional critical questions should be added.

(1) In modeling population exposures, which sets of NHEXAS study measurements are expected to provide representative population exposure distributions in each of the study areas?

(2) For which pollutants/media, are the NHEXAS data sufficient to develop, calibrate, and evaluate multimedia, multipathway exposure models?

(3) What types of route and pathway-specific microenvironmental exposure models can be developed or tested with the available NHEXAS demographics, concentration, questionnaire, time/activity, and dietary data?

(4) What approaches or optimal methodologies/models can be used to estimate pathway-specific exposures and dose?

(5) What are some suggested strategies for integrating media and pathway-specific exposures and dose estimates?

(6) What models best describe the relationship between the short-term NHEXAS measurements and long-term exposures?

(7) What is the comparison of modeled dose estimates and biomarkers?

(8) What models should be developed and applied in order to identify factors related to high-end exposures?

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[4]Numbers in brackets are cross-references to sections in the SAB report.

(9) What are the model input uncertainties using the NHEXAS data, and what are the resulting uncertainties in the exposure and dose model predictions?

(10) What model analyses should be used to determine how much uncertainty in exposure measurements can be reduced by collecting more detailed measurements on exposures, pollutant concentrations, and different exposure factors?

(11) What is the influence of the spatial and temporal scales in concentration and exposure measurements based on NHEXAS data and model predictions?

(12) What is the comparison of the exposure and media-specific concentration distributions from the initial (pre-NHEXAS) exposure assessments to the NHEXAS pilot results?

(13) How can the initial pre-NHEXAS study multimedia, multipathway models developed for lead, benzene, and chlorpyrifos using the NHEXAS study measurements be verified or extended?

(14) How can the multipathway exposure and dose models using the NHEXAS data and other data sets be best calibrated and evaluated?

(15) What NHEXAS analyses will benefit ongoing modeling projects such as TRIM and CEM?

4.5.3 Discussion Considerations

In discussing and developing proposals for the analyses (or projects) identified above, consider the following questions.

(1) What statistical or analytical techniques should be used to address the analysis or modeling issues raised by the questions?

(2) What approaches are best suited for estimating averages and upper percentiles of the exposure and dose distributions for the different population subgroups (e.g., children, adults, elderly)?

(3) How should NHEXAS data across the consortia be treated in modeling exposures and dose? Should the data sets be combined or treated separately?

(4) How can we model exposures to multiple pollutants?

(5) What analyses or modeling studies should be conducted in order to design future field studies that will improve the current and new multimedia, multipathway modeling projects?

4.5.4 Project Descriptions

Project Name:	**M-1. Review Format and Content of NHEXAS Databases for Modeling Utility**
Short Project Description:	This project will examine the NHEXAS database and establish optimal format required for exposure modeling projects. Other users should be included in this process to maximize utility of the combined database.
Goal/Objective:	NHEXAS data must be available in a format that is readily accessible to potential users. Data should be accessible for input to existing models to allow for model testing and investigation of NHEXAS relationships (i.e., correlations among various dependent and independent variables). Models that are being developed or expected to be developed in the future are also likely to require standard database formatting, which should allow for convenient access and inquiry.
Significance of Project:	An essential first step prior to pursuing any other NHEXAS modeling project.
Suggested Approach:	Review existing exposure models to assess model input needs and to compare with available NHEXAS data. Confer with NHEXAS study data developers, exposure model developers, and other potential NHEXAS data users to establish the optimal format for NHEXAS database. Establish a task force (or committee) and/or hold a workshop to set a standard for the present and future NHEXAS databases.
Data or Input Needs:	Data from all three NHEXAS studies including data code books, final databases, and QA/QC data.
Feasibility (of analyses with current NHEXAS databases):	This project is of the utmost importance since the availability and format of the NHEXAS database will affect directly the success of interpreting the results of NHEXAS. Because the preparation of the NHEXAS database is already underway, it is feasible and necessary to give this proposed project high priority. In particular, this project could benefit from the ongoing database projects at the three NHEXAS consortia.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Convene workshop
	Month	12	(3) Final outputs: Report summarizing workshop findings and conclusions
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	30	12	Principal investigator/EPA Coordinator
	50	12	Senior-level staff (“associate”)
	50	12	Junior-level staff (“assistant”, technician), students
			Other (describe): Task force of EPA and approximately 10 external experts who will participate in at least one workshop

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-2. Evaluation of Existing Multimedia Models Using the NHEXAS Data Set**
Short Project Description:	High-quality and reliable multimedia monitoring data are virtually nonexistent in the literature, and, as such, the opportunity to test existing models, even on a qualitative scale, is rarely available. Several multimedia models have been developed, or are under development, that predict media concentrations in residential environments based on inputs such as source characterization and fate and transport, etc. Information available from the NHEXAS questionnaires, particularly those related to local source characterization, fate and transport, receptor characterization and activity patterns (supplemented by default values) should be analyzed and used in these models to predict media concentrations and personal exposures of the NHEXAS respondents. These predictions should be compared with the individual's exposures and microenvironmental concentrations monitored in NHEXAS. Examples of models that can be evaluated include, but are not limited to, TRIM, MEPAS, CARES, LIFELINE, and CONSEXPO, as well as other linked and nested compartmental models.
Goal/Objective:	• To improve the understanding of the strengths and limitations of existing multimedia models and identify opportunities for improving current and future models. • Identify the usefulness of the data set and determine how future NHEXAS studies could better meet the need for testing models.
Significance of Project:	Multimedia models provide the basis for regulatory decision for pesticides, hazardous waste sites, and the evaluation of releases to air and water. Currently, there are very limited opportunities to evaluate these models. NHEXAS provides a unique opportunity for such evaluations.
Suggested Approach:	This project would be performed in phases. (1) Determine how the data set could be used (selection of pollutants, interim findings, activity/dietary patterns, etc.). (2) Identification of the models, modeling strategies (e.g., linked and nested multimedia models) and the development of the strategy for developing model inputs and relating outputs to the dose measurements in the NHEXAS data set. (3) Model teams (preferably the developers of each multimedia model) perform the evaluations. (4) Analyze the model's prediction and NHEXAS findings to determine how and why the models did or did not match with the survey. (5) Develop recommendations on how future NHEXAS projects could be better designed to meet the evaluation needs of multimedia modelers. (6) Publish a final report/peer review publication. Tasks 1 and 2 could be performed by a panel of exposure assessment experts, through one or more workshops. Where possible, model owners should be involved in these workshops. A clear methodology should be established for the evaluation procedures. The selected models should be divided into modules, if possible, for estimating intermediate and final exposure results. Modules should include source characterization, fate and transport, receptor characteristics, activity patterns, and exposure assessment (Task 3). A consistent strategy for dealing with data gaps should be established. The model's predictions of interim findings (air and surface levels, hand wipe, dietary levels, activity patterns, etc.) also should be compared to the NHEXAS data set.
Data or Input Needs:	The complete data set (including the data from the questionnaires) should be available prior to the development of the specific model test sets. Models should be well characterized and model developers should participate in the project.

Feasibility (of analyses with current NHEXAS databases):	The project should be feasible. Only existing models will be evaluated. Where appropriate, model developers will be included in the project team. Models of many source terms cannot be included in this exercise because they were not included in NHEXAS.

Project Name:	**M-2 (cont'd). Evaluation of Existing Multimedia Models Using the NHEXAS Data Set**		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Selection of models for evaluation, development of a modeling strategy that addresses differences in the type of models and how data gaps will be addressed
	Month	12	(3) Development of a charge to the individual running the models
	Month	18	(4) Final outputs: Report/peer review publication
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	40	18	Principal investigator
	100	18	Senior-level staff ("associate")
	80	18	Junior-level staff ("assistant", technician), students
			Other (describe): Two to three workshops are anticipated

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-3. Develop Model Parameters from Qualitative and Quantitative NHEXAS Monitoring Data, Questionnaires, Time/Activity, and Survey Data**
Short Project Description:	Develop exposure model parameter (e.g., ingestion rates, emission rates, etc.) values, ranges, and distributions making use of both quantitative and qualitative data generated in NHEXAS. Exposure parameters should be developed in accordance with the current state of the art in exposure assessment and corresponding model input requirements. Specific emphasis should be placed on key exposure parameters common in multimedia exposure assessment and those that are likely to contribute to high-end exposures.
Goal/Objective:	Generate deterministic values and stochastic distributions for exposure model parameters, using available NHEXAS database. Exposure parameters that are selected should be relevant to exposure assessments that are based either on mechanistic, statistical, or empirical models.
Significance of Project:	Improve exposure parameter values and the utility of questionnaires for quantitative exposure analysis.
Suggested Approach:	Develop methods to interface available selected exposure models with qualitative and quantitative questionnaire data (e.g., time/activity patterns, identified sources and exposure pathways) for the purpose of deriving magnitude, ranges, and distributions of exposure parameters. The combination of artificial intelligence and statistical methods is one possible approach for the automated analysis of large data sets.
Data or Input Needs:	NHEXAS chemical monitoring data for all media (where available) and qualitative/quantitative data generated from questionnaires and other sources (e.g., local survey of potential sources).
Feasibility (of analyses with current NHEXAS databases):	The use of mathematical and computer methods to combine qualitative and quantitative data for the purpose of generating quantitative exposure parameters represent a new and challenging approach. The proposed approach is feasible given the rich NHEXAS database and existing state-of-the-art mathematical methods of quantifying descriptive data in the context of model development. Analysis may be limited by censored (e.g., nondetects) data for chemical measurements in some media.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Development of methodology and demonstration of general test cases (Phase I)
	Month	24	(3) Final outputs: Final report and peer reviewed papers
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	50%	24	Principal investigator
	100%	24	Senior-level staff ("associate")
	50%	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-4. Quantify Uncertainties in NHEXAS Data and Assess Contribution to Model Errors**
Short Project Description:	Provide uncertainty estimates within the NHEXAS database that are available to researchers and the public, so that uncertainty is addressed consistently and does not lead to redundant effort by modelers. Identify how the data uncertainties may impact modeling uncertainties and illustrate with case studies.
Goal/Objective:	• Provide consistent, understandable uncertainty estimates of the NHEXAS data within the NHEXAS database • Provide guidance/advice on applicability and use of various types of data in models to minimize inappropriate model construction.
Significance of Project:	The NHEXAS database will be used by many researchers and the public. Inclusion of uncertainty estimates/descriptions will avoid duplication of effort in calculating these values, will mean that the data uncertainties are treated consistently, and will alert the public and regulatory community of possible limitations in the use of the data.
Suggested Approach:	Analytical Measurements (1) Ensure that NHEXAS data are QA'd and flagged appropriately. (2) Ensure that NHEXAS data include Limit of Detection information. (3) Calculate standard errors for each analytical methodology (including sampling and analysis). (4) Tag uncertainty data to all NHEXAS data entries and provide a methodology for error estimation with the public database. Survey and Time/Activity Information (1) Provide qualitative assessments of data and their applicability for modeling by including meta data from field staff on reliability of individual household; include expert panel judgment of uncertainties of the methodology in general, including effects of sample size, inaccuracies of recall diaries, observer effects, time resolution effects, etc.; and compare survey results from NHEXAS with other data sources. (2) Include qualitative assessments in database. Assessment of Model Uncertainties Convene workshop of modelers to evaluate impacts of uncertainties for variety of analytes, with differing critical routes of exposure. Provide qualitative descriptions of uncertainties and caveats for inclusion in the database. Provide case studies to illustrate how errors impact modeling uncertainties.
Data or Input Needs:	Paced by the availability of the database, the NHEXAS data need to be quality assured to flag/remove inappropriate data. Duplicate sample data, split sample data, blanks, and other QA/QC information on the analytical measurements need to be included in the database. A description of the sampling and analytical methods also must be included.
Feasibility (of analyses with current NHEXAS databases):	The first part of the effort is quite doable, and should build on normal QA/QC procedures. This work is to insure that the synopsized uncertainty data also are made readily available for researchers and the public. The impact on modeling errors is much more likely to be case dependent, varying with each analyte and model used.

Project Name:	M-4 (cont'd). Quantify Uncertainties in NHEXAS Data and Assess Contribution to Model Errors		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	2	(2) Review NHEXAS databases now under development for data to be included and make sure that QA/QC data and metadata on QC are in database for both analytical and survey data
	Month	3	(3) NHEXAS database becomes available
	Month	6	(4) Calculate synopsis information from data sets now scheduled to be delivered in FY01
	Month	6	(5) Convene workshop or expert panel to provide qualitative description of uncertainties associated with survey information
	Month	6	(6) Convene workshop or expert panel to evaluate impact of uncertainties of modeling–prepare case studies for specific analytes/major routes of exposure
	Month	12	(7) Final outputs: Incorporate uncertainty estimates and case studies into public database
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	n/a *	11	Principal investigator (PI)
	n/a *	6	Senior-level staff ("associate")
	n/a *	6	Junior-level staff ("assistant", technician), students
	n/a *	5	Other (describe): Clerical

* Duration = approximate time (in months) needed, from start of project, to complete each step.

* **NOTES:** Level of Effort [FTE equivalent] estimates:

Review NHEXAS database:
: 0.5 mo PI level * 6 PI (3 external experts +1 from each of 3 consortia) [3 mo]; 0.5 mo senior level at each of 3 consortia [1.5 mo]; 0.5 mo junior level staff at each of 3 consortia [1.5 mo]; 0.5 mo clerical staff at each of 3 consortia + 0.5 mo general support [2 mo].

Calculate synopsis uncertainty data from database:
: 1 mo. senior level [1], 1 mo junior level [1].

Workshop on Survey uncertainties:
: 0.5 mo for 6 PI level experts [3.0]; 0.5 mo clerical support [0.5].

Workshop on modeling errors:
: 0.5 mo for 6 PI level experts [3.0]; 0.5 mo clerical support [0.5].

Develop case studies:
: 0.5 mo for 3 PI level experts [1.5], 1 mo for 3 senior level [3], 1 mo for 3 junior level staff [3].

Incorporation into database:

0.5 mo PI level, 0.5 mo senior level, 0.5 mo junior level, 2 mo clerical support.

Project Name:	**M-5. Incorporation of Modeling Considerations in the Design of Future NHEXAS Studies**
Short Project Description:	In conducting field studies, usually a study is designed, monitoring data and other related data are gathered and then statistical analyses performed to interpret the data. However, from a model development, model application, or model evaluation perspective, the data gathered may be insufficient (particularly for inferential purposes). Future NHEXAS studies should accommodate the needs of existing or modified multimedia models. To achieve this, the model parameters should be understood and incorporated in the study design. Sample parameters include those related to time/activity patterns, contact rates, dermal exposure (e.g., surface coverings in residences, time spent on these surfaces).
Goal/Objective:	To establish a procedure wherein modeling considerations are accommodated in the early stages of the design of future NHEXAS studies.
Significance of Project:	The power of any future NHEXAS study lies in interpreting the measurement results within the risk assessment/risk management paradigm used by EPA to select actions designed to protect the public. This interpretation can be done effectively only through modeling the exposures and the changes resulting from the risk management actions. It is critical that future NHEXAS field studies incorporate modeling considerations in their design from the very inception to ensure their usefulness for protecting human health and the environment.
Suggested Approach:	The results of the NHEXAS pilot studies can be used to identify a multimedia exposure assessment methodology, either currently implemented in a model or that can be later modified. This methodology can be used to establish the parameters to be monitored in future studies.
Data or Input Needs:	All available data from NHEXAS pilot studies.
Feasibility (of analyses with current NHEXAS databases):	This project is immediately feasible and should be undertaken before any future NHEXAS studies.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Determine model parameters to be monitored
	Month	6	(3) Final outputs: Demonstrate use of poststudy data
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	50	9	Principal investigator
	50	9	Senior-level staff ("associate")
			Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-6. Identification of Factors Contributing to High-End Exposures in the NHEXAS Study**
Short Project Description:	Determine factors (activities, sources, and housing or personal characteristics) that contribute to the upper region of the exposure distribution, as well as to exposures received by sensitive members of the population (e.g., children and the elderly). Ideally, factors will be revealed for pollutants each representing a chemical type (VOCs, metals, and pesticides). A variety of statistical methods may be appropriate for investigating the complete range of the NHEXAS data, including analytical, questionnaire, and time/activity data.
Goal/Objective:	Identify the major contributions, routes, and sources, to high-end exposures for different classes of pollutants.
Significance of Project:	Identification of the factors that influence or contribute to exposure is necessary for interpretation of the NHEXAS data, applying the results to risk assessments and identification of remedial actions. Analysis of the data could indicate which questionnaire items or activities may be suitable for predicting high exposures or where additional targeted questions may be necessary.
Suggested Approach:	There are a variety of methods that may be applicable to this project. Suitable methods should be able to handle a variety of data types (binary, integer, categorical, ordinal, and continuous), possibly after suitable transformations of the data. Potential methods may be based on regression trees, neural networks, or factor analysis. Methods of order statistics (i.e., statistics of extreme events), not previously used in exposure assessments, also may reveal important relationships.
Data or Input Needs:	Investigators will need to construct a distribution of exposure using environmental concentrations and exposure factors, or biomarkers. The criteria for identifying individuals at the high end then will need to be determined.
Feasibility (of analyses with current NHEXAS databases):	The proposed types of analyses will be applicable for only chemicals where a comprehensive set of measurements for an adequate number of subjects exists. Some methods also may require a substantial number of properly classified subjects to "train" a model. Potential chemicals for which comprehensive data appear to exist are metals, chlorpyrifos, and benzene.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: On availability of NHEXAS data; timeline based on the analysis of three pollutants (metal, VOC, and pesticide)
	Month	3	(2) Obtain and merge databases
	Month	9	(3) Develop estimate of exposure and fit a possible distribution
	Month	12	(4) Identification of highly exposed individuals
	Month	18	(5) Development or training of models
	Month	24	(6) Final outputs: Draft manuscript detailing potential important factors and sources of uncertainty in the identification
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	20	24	Principal Investigator

	50	24	Senior-level staff ("associate")
	50	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-7. Implementation of Existing Multimedia/Pathway Exposure Models To Aid in the Interpretation of NHEXAS Data**
Short Project Description:	Multimedia fate and exposure models have been constructed to represent the current state of the science regarding chemical, environmental, and populations dynamics. These models are powerful tools for investigating NHEXAS data. These investigations should help to identify critical exposure pathways and factors that contribute to high-end exposures. In short, these models can aid to better understand and explain results from the NHEXAS project and to design future studies.
Goal/Objective:	Utilize existing multimedia/pathway exposure models to aid the interpretation of NHEXAS data and to help identify critical exposure pathways, processes, and factors that contribute to high-end exposures.
Significance of Project:	This project is significant in that it will utilize existing tools that assimilate or represent the current level of understanding of fate and exposure processes to extract relevant and useful information from the NHEXAS results.
Suggested Approach:	(1) Ideally this project should include at least one pesticide, a semi-volatile compound (with differing source characteristics than the pesticide, such as a PAH), and a metal. (2) For each chemical class, identify specific case studies within NHEXAS that warrant investigation (elevated concentrations in multiple media, elevated exposure, sensitive populations [children]). (3) Summarize and utilize available and appropriate data. (4) Augment missing input data using a combination of alternative data sources, parameter space analysis techniques, and expert judgment. (5) Utilize various methods in forward model application and inverse modeling to identify critical pathways, processes, and assumptions in the models. (6) Develop plausible explanations for survey results. (7) Prepare a report and/or peer review publication.
Data or Input Needs:	• NHEXAS data to include monitoring results, time/activity data, food/water intake data, and source data, when available and appropriate. The analysis will benefit from including information from other data sources. • Other data sources may include the Toxics Release Inventory (TRI), population density, local and regional pesticide use records and other information that might be useful in approximating/constructing source term information.
Feasibility (of analyses with current NHEXAS databases):	Several models are already available that can be used to aid in the interpretation of NHEXAS data, and many of the methods that utilize these existing models are established. Effort will need to be directed at identifying appropriate case studies within the survey results.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Identify important case studies with input from EPA

	Month	12	(3) Complete paramaterization of selected case studies and select models
	Month	18	(4) Complete initial evaluations and produce concept draft report
	Month	24	(5) Final outputs: Submit final report or draft manuscript for peer review
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	30	24	Principal investigator
	100	24	Senior-level staff ("associate")
	50	24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-8. Investigate Stability of Individuals in Population Exposure Ranks Over Time**
Short Project Description:	Temporal variability in measurements of individuals may have a significant effect on estimates of exposure factors and distributions. This project will investigate the effect of using cross-sectional studies on estimates of exposure factor distributions. Cross-sectional studies are cost efficient because they collect minimal observations per individual, but provide no indication of temporal variability. Measures of intraindividual temporal variability do not necessarily tell the complete story, as individuals may vary in concert, because of factors such as seasonal changes. It is also useful to examine the stability of individual's position or rank in the population exposure distribution to determine how this stability influences predictive ability of various exposure distribution parameters.
Goal/Objective:	To examine the importance of temporal variability and evaluate sources of variability in exposure factor measurements of an individual over time. To examine this variability on stability of an individual's rank or position in exposure factor population distributions.
Significance of Project:	It is important to understand the temporal variability in individual's measurements to assessment of potential bias of cross-sectional studies as estimates of exposure factor population distributions. A clear understanding of temporal variability will be useful in deciding when and where cross-sectional studies are appropriate for estimation of population exposure distributions and what modifications may improve these studies in a cost-efficient manner. This work also would provide highly relevant information on estimating the upper tails of the distribution.
Suggested Approach:	(1) Identify feasible and relevant variables from NHEXAS for study. (2) Develop/assess methods for examining temporal variability and stability of individuals. (3) Use mixed models to develop repeated measure/temporal correlation estimates and consider automation of methodology for examination of large numbers of variables.
Data or Input Needs:	The entire NHEXAS data set, especially the Maryland NHEXAS longitudinal data.
Feasibility (of analyses with current NHEXAS databases):	Feasible for variables where longitudinal data are collected for at least some individuals. Focus is likely to be on the Maryland study, with confirmation/validation use of Region V and Arizona NHEXAS studies.

Project Name:	**M-8 (cont'd). Investigate Stability of Individuals in Population Exposure Ranks Over Time**		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Develop methods for examining temporal variability and stability of individuals
	Month	18	(3) Apply mixed models to develop repeated measure/temporal correlation estimates
	Month	24	(4) Final outputs • Determination of factors influencing temporal variability in individuals exposed to environmental pollutants • Identification of limitations of cross-sectional population exposure surveys and recommendation of optimal spatio-temporal survey designs for future NHEXAS-type studies
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	15-20	24	Principal investigator
			Senior-level staff ("associate")
	50 50 50	24 24 24	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-9. Reconstruct Exposure and Dose Profiles from Biomarker Data Utilizing Questionnaire and Environmental Measurements**
Short Project Description:	The relationships among environmental measurements, time/activity data, and biomarker levels will be investigated with the goal of classifying exposure scenarios into steady-state cases (e.g., from long-term average exposures) and intermittent events. There are several assumptions regarding the route and timing of dose that need to be addressed in making these estimates, and the questionnaires and time/activity data will be used to make these determinations. There is the potential to focus on the exposures of children, in addition to the general population.
Goal/Objective:	To develop and evaluate a methodology that provides realistic estimates of the dose and exposure associated with a biomarker measurement as a function of the types of exposure that occurred.
Significance of Project:	Biomarkers can provide an indicator of total absorbed dose. However, making quantitative estimates of this dose requires several assumptions about the timing and route of the exposures, as well as the suitability of the model being used. The estimates of total absorbed dose may help to evaluate current exposure assessment models and assumptions (e.g., Office of Pesticide Programs' [OPP's] Residential SOPs) and to develop and test models describing residential exposure.
Suggested Approach:	• The total absorbed dose from a steady-state exposure will be modeled by a mass-balance, and the absorbed dose from discrete events will be estimated by an inverted pharmacokinetic model (in the case of compact classical compartmental models) or maximum likelihood optimization procedure (in the case of comprehensive physiologically based models). • These dose estimates will be linked to a range of possible exposures and environmental concentrations and then compared with those measured in the NHEXAS study. Differences will reveal areas of improvement for modeling methods and indicate additional information that will be useful to collect in future studies.
Data or Input Needs:	• Pollutant concentrations in solid-food, personal air, dermal rinse, surface press and wipe, urine (pesticide metabolite), and measurements. • Pesticide use from household screening, baseline, and follow-up questionnaires. • Time/activity and food consumption diaries. • Information on urine volume, creatinine concentration, time of last void, and body weight.
Feasibility (of analysis with current NHEXAS databases):	This project can be implemented in a 2-year time period assuming the availability of the NHEXAS database. Likely candidate chemicals are chlorpyrifos, lead, arsenic, and benzene. • The food diaries may not be coded to link with ranges of pesticide residues (by food type), which may limit the temporal resolution of the dietary data estimates. • There are concerns about applying model parameters (e.g., absorption and elimination rates) determined in a small number of individuals to the general population because of differences in personal characteristics such as age, gender, race, and health status.

Project Name:	M-9 (cont'd). Reconstruct Exposure and Dose Profiles from Biomarker Data Utilizing Questionnaire and Environmental Measurements		
Approximate Project Time Table and Level of Effort			
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project: On availability of NHEXAS data; timeline based on the analysis of a single pollutant
	Month	3	(2) Obtain and merge databases
	Month	6	(3) Analysis of questionnaire/activity data to group by types of exposure
	Month	9	(4) Review metabolite data by individual to identify intermittent and steady-state patterns
	Month	12	(5) Solving and programming the models
	Month	18	(6) Incorporation of the model in an estimation methodology
	Month	21	(7) Uncertainty analysis
	Month	24	(8) Final outputs: Draft manuscript on approaches to estimate chlorpyrifos dose from a biomarker and exposure information
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	24	Principal investigator
	50 25	24 03	Senior-level staff ("associate")
			Junior-level staff ("assistant", technician), students
	10	2	Other (describe): Consultant (statistical)

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-10. Use NHEXAS Dietary and Activity Pattern Data to Develop Predictive Relationships Between Single Day Observations and Long-Term Patterns of Behaviors**
Short Project Description:	To use statistical techniques to determine the relationships between measurements of exposure-related behaviors (e.g., dietary and activity patterns) on a single day and subsequent longitudinal measurements. Use the short-term relationships to develop predictive models of longer term behaviors. The NHEXAS data set provides a unique source of information for this study.
Goal/Objective:	To develop models of the relationship between short- and long-term measurements of exposure-related behaviors that can be used in models of long-term exposures.
Significance of Project:	Collection of longitudinal data on exposure-related activities are resource intensive and subject to a number of technical difficulties. However, such data are critical to the accurate estimation of dose rates over periods longer than a single day.
Suggested Approach:	Longitudinal data on exposure-related behaviors will be extracted from the data set. Statistical techniques such as, but not limited to, random walk, Markov chains, correlation, and pattern recognition will be investigated as potential tools to identify relationships between short- and long-term patterns of behaviors. It is anticipated that the relationships will vary greatly across behaviors. No one method is likely to predict the relationship between short- and long-term behavior. Attention should be given to developing methods of estimating the upper bound of long-term behaviors as a function of short-term data. Patterns in time/activity data from the Maryland NHEXAS study should be compared/contrasted with data collected in the Region V and Arizona NHEXAS studies. Certain endpoints such as dietary records should be compared to the results of other longitudinal dietary studies to determine consistency across different populations.
Data or Input Needs:	The NHEXAS data set and other studies of long-term dietary patterns.
Feasibility (of analyses with current NHEXAS databases):	The data for this task are available. No limitations are anticipated.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	4	(2) Extract data for data set
	Month	4	(3) Obtain other dietary surveys
	Month	4	(4) Reconcile differences in dietary survey methods
	Month	12	(5) Perform Statistical analyses
	Month	18	(6) Final outputs: Develop final report
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	18	Principal investigator
	30	18	Senior-level staff ("associate")
	20	12	Junior-level staff ("assistant", technician), students

			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: Dietary studies may be performed using different recording methodologies.

Project Name:	**M-11. Identify and Investigate Exploratory Data Analysis Methods That Are Appropriate for Providing Additional Insights into NHEXAS Output**
Short Project Description:	Several different methods are now available for analyzing complex data sets to identify patterns, relationships, sociodemographic variables, important factors, and combinations of factors that influence or affect exposure distributions.
Goal/Objective:	Identify useful and appropriate tools for investigating large and complex data sets such as NHEXAS. Specifically, there is a need to identify the factors that contribute to high exposures and establish relationships among these factors and exposure magnitudes/distributions.
Significance of Project:	It is essential that one understand the data prior to using it for model evaluation or identification of significant exposure pathways/processes. Several data analysis methods are available that are based on neural networks, principal component analysis, multiple regression, CART, and other techniques. These various methods or approaches that are designed to investigate complex data sets should be compared and contrasted in order to determine the most appropriate approach for identifying important contributing factors in the NHEXAS data.
Suggested Approach:	(1) Develop general case studies using NHEXAS data, as well as that of other national data-rich surveys (NHANES, NHAPS, CSFII), and investigate the ability of various data analysis tools to identify characteristics of the data. (2) Identify strengths and limitations for each method in relation to the NHEXAS data. (3) Recommend appropriate methods for analyzing NHEXAS data with special attention paid to the upper tails of the distributions.
Data or Input Needs:	The fully compiled database containing results from each of the NHEXAS surveys, including exposure, chemical, activity, dietary and socio-demographic variables.
Feasibility (of analyses with current NHEXAS databases):	The large number of qualitative and quantitative data types included in the NHEXAS data sets (ordinal, continuous and binary) require special consideration when identifying appropriate methods or approaches used to analysis data. Attention should be given to the upper tails of the exposure distributions.

Project Name:	**M-11 (cont'd). Identify and Investigate Exploratory Data Analysis Methods That Are Appropriate for Providing Additional Insights into NHEXAS Output**

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	3	(2) Finalize list of models/methods to include in study
	Month	10	(3) Complete baseline analysis/comparison
	Month	10	(4) Submit concept draft for review
	Month	12	(5) Final outputs: Final report or manuscript for submission to peer review journal
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	30	12	Principal investigator
	100	12	Senior-level staff ("associate")
	50	12	Junior-level staff ("assistant", technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: Clearly the time and effort required for this project will depend on the models/methods that are included in the comparison and analysis. The number of appropriate methods can be reduced by the constraint introduced by the wide range of data types in the survey data. This may need to be addressed in a preliminary 3- to 6-month investigation designed to identify candidate models or methods for inclusion in the study.

Project Name:	**M-12. Investigate National Representativeness of NHEXAS Sampling Results by Comparing Measurement and Exposure Results Across the Three Regions**
Short Project Description:	Very few national studies are available for use in development of national exposure distributions; therefore, local or regional studies are used instead. The question then is raised about the effect of using this restricted information on national exposure estimates. The three NHEXAS studies provide a method for comparing very similar studies to determine the magnitude of regional differences for various exposure factors.
Goal/Objective:	To determine bias in estimates of national exposure factors and distributions by use of local or regional sampling represented by NHEXAS pilot studies.
Significance of Project:	The information provided by this project also will advance knowledge of uncertainty in model parameters used in a variety of exposure models. The information also will help to ascertain the geographic scale at which variables may be collected in future studies.
Suggested Approach:	Examination of sample population distributions for various measurements collected in all three studies. Examination should be based on current methodologies as much as possible to facilitate quick turnaround. Appropriate analysis methods used to determine "similarity" between studies and quantification of uncertainty should be based on methods that provide simple, robust measures as feasible.
Data or Input Needs:	NHEXAS data from all three studies.
Feasibility (of analyses with current NHEXAS databases):	Study should be feasible. Possible difficulties may arise for some variables where collection methods differ among studies.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	2	(2) Collect and gain familiarity with study data
	Month	8	(3) Develop/assess framework for comparing study measurements
	Month	9	(4) Implement automation of comparisons
	Month	10	(5) Run analyses for selected variables
	Month	12	(6) Final outputs: Report on regional differences between studies, suggested values for use in national exposure models and values of uncertainty.
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	12	Principal investigator
	25	12	Senior-level staff ("associate")

	50 50	12 12	Junior-level staff (“assistant”, technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-13. Evaluate Implications of NHEXAS Results for Existing Chronic Exposure Assessments Methodologies**
Short Project Description:	Screening models (sets of algorithms) are used widely to make preliminary decisions for Superfund sites, pesticide regulations, and the evaluation of emissions to air and water. However, high quality and reliable multimedia monitoring data to validate these models are virtually nonexistent in the literature, and, as such, the opportunity to test screening models, even on a qualitative scale, is rarely available. This project will take the dose estimates from personal monitoring or biomarkers and compare the estimates to those produced from EPA screening methodologies (also referred to as Tier 1 or initial Tier assessments). Examples of these methods include recommended exposure models under the Superfund program and the residential SOPs.
Goal/Objective:	To improve the understanding of the strengths and limitations of existing screening models and identify opportunities for improving future models.
Significance of Project:	Screening models provide the basis for preliminary regulatory decisions for pesticides, hazardous waste sites, and the evaluation of releases to air and water. NHEXAS databases provide a unique opportunity to evaluate these models.
Suggested Approach:	This project would be performed in phases, (1) Determine how the NHEXAS data set would be used (selection of pollutants, interim findings, activity/dietary patterns, etc.). (2) Development of the strategy for developing model inputs and relating outputs to the data set. (3) Perform the evaluations. (4) Analyze the results to determine why the models did or did not match with the survey. (5) Publish a final report. A clear methodology should be established for the evaluation procedure that will be reviewed scientifically. A consistent strategy for dealing with data gaps should be established.
Data or Input Needs:	The complete data set (including the data from the questionnaires) should be available prior to the development of the specific model test sets. Participation from the relevant EPA program offices is desirable to confirm detail on how screening exposure models actually are used.
Feasibility (of analyses with current NHEXAS databases):	The project is feasible with the indicated data resources.

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	6	(2) Development of a modeling strategy that addresses differences in the type of models and how data gaps will be addressed
	Month	12	(3) Final outputs: Report/peer review publication
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	12	Principal investigator

	30	12	Senior-level staff ("associate")
	20	9	Junior-level staff ("assistant", technician), students
			Other (describe): Two meetings

* Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: This project could be run in conjunction with Project M.

Project Name:	**M-14. Development and Evaluation of Models for Interpreting and Quantifying Inter- and Intraindividual Variability in Pesticides Exposure/Dose Using NHEXAS Data**
Short Project Description:	Analyze cross-sectional and longitudinal biomarker and exposure data for pesticides considered in NHEXAS (such as chlorpyrifos and atrazine) to develop and test population-based pharmacokinetic (i.e., pharmacostatistical) models that explicitly discern and quantify intra- and interindividual variability in human doses.
Goal/Objective:	To develop, test/evaluate, and make available to EPA and the scientific community at large, a mechanism-based computational tool for characterizing and quantifying inter- and intraindividual variability (i.e., cross-sectional and longitudinal variability) in pesticides exposure/dose of human populations.
Significance of Project:	Quantitative characterization of inter- and intraindividual dose (and corresponding exposure) to common pesticides will reduce the uncertainty in, and thus improving, relevant dose/response studies and corresponding risk assessments. The mechanistic approach to be developed and evaluated should be applicable to a wide range of exposure situations and U.S. population segments.
Suggested Approach:	(1) Develop general formulations for population-based (pharmacostatistical) models of selected pesticides considered in NHEXAS (primary candidates are chlorpyrifos and atrazine) that explicitly incorporate/describe inter- and intraindividual variability of biological uptake/distribution/fate. This step primarily should consider existing "individual-based" "classical" (compartmental) models, as well as the possibility of formulating simplified population physiologically based models. (2) Perform analyses of appropriate NHEXAS data components to develop parameterizations for the above formulations (the Maryland study database being the primary candidate because it contains extensive longitudinal data); assess and interpret magnitudes of different types of variability. (3) Test the population pharmacostatistical model, with parameterizations derived as in the step above, with relevant independent data from other NHEXAS components to evaluate its ability to reproduce variability observed in these studies. (4) Review the available literature for other relevant data sets that may exist on dose variability for the pesticides of concern and extend the model evaluation to include these data sets. (5) Finally, evaluate the new model/method for its applicability to children's exposure to pesticides (using the NHEXAS Minnesota study data) and derive recommendations for appropriate model refinements/modifications and possibly additional data collection that would help to extend the model to children's exposure.
Data or Input Needs:	Pesticide exposure- and dose-related data from all three NHEXAS studies; other exposure/dose-related data from these studies (from both monitoring and questionnaires), such as activity patterns and additional literature data

Feasibility (of analyses with current NHEXAS databases):	At a minimum, it should be feasible with the collected data to at least evaluate the applicability of a population-based pharmacokinetic model for pesticide dose estimation to multiple regions and population segments of the United States. In some cases, biological half-life considerations may influence the modeling choices. In the best case, a widely applicable tool will be available; in the worst case, data needs for characterizing nationwide variability to dose will be identified.

Project Name:	**M-14. Development and Evaluation of Models for Interpreting and Quantifying Inter- and Intraindividual Variability in Pesticides Exposure/Dose Using NHEXAS Data**		

Approximate Project Time Table and Level of Effort

Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	12	(2) Data analysis/evaluation Comparison and evaluation of existing approaches for individual-based pharmacokinetic modeling of the selected pesticides
	Month	24	(3) Final outputs: Tested operational population-based model with explicit descriptions of inter- and intraindividual variability Peer-reviewed manuscript
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	24	Principal investigator
	75	24	Senior-level staff (“associate”)
	100	24	Junior-level staff (“assistant”, technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-15. Comparison of NHEXAS Findings with Cumulative Exposure Project Estimates for Ambient Air Levels and Exposures for Selected VOCs and Metals**
Short Project Description:	Compare patterns and trends in monitored neighborhood ambient air levels of VOCs and metals to the annual average estimates of the same compounds derived through the Cumulative Exposure Project (CEP); evaluate the relevance of CEP predictions to the types of exposure situations characterized in NHEXAS.
Goal/Objective:	To evaluate the relevance of CEP predictions to the types of exposure situations characterized in NHEXAS; to identify gaps and potential improvements in both screening modeling methods for ambient air quality characterization and in data collection for exposure characterization.
Significance of Project:	The CEP study has attracted remarkable attention, including the media's and the general public's, as well as some criticism regarding its relevance to exposures actually experienced by individuals and populations. This project will help in understanding and characterizing both the relevance and the limitations of CEP (and potentially of similar approaches), as well as in identifying specific steps in improving exposure estimates to airborne contaminants through screening modeling approaches.
Suggested Approach:	(1) Extract ambient air concentration estimates from the 1990 CEP database (or from the follow-up database utilizing more recent TRI emission data, depending on its availability at the time of project implementation) for a set of selected airborne VOCs and metals monitored in the NHEXAS studies and for the approximate locations of the monitors. (2) Incorporate both the CEP estimates and the corresponding NHEXAS observations in a Geographic Information System linked with appropriate statistical/geostatistical software routines to ensure maximum usability, visualization, and analysis options for these data and estimates. (3) Perform qualitative and statistical comparisons of relevant ambient air concentration estimates/data from CEP and NHEXAS, with focus on identifying general patterns and trends. (4) Perform screening calculations of exposure for selected subsets of the NHEXAS components, using the CEP estimates as the starting point and utilizing partial information from the NHEXAS databases (such as activity patterns and other questionnaire-based information). Compare these results to personal exposure measurements and estimates that utilize additional NHEXAS data. (5) Consider, evaluate conceptually, and, if possible, investigate through limited case-specific studies, potential improvements in CEP-type methodologies for screening ambient and exposure characterization.
Data or Input Needs:	For phase I (steps 1 to 3 of the approach), NHEXAS monitored selected VOCs and metals with corresponding geographical location information. CEP data are publicly available but certain additional information may need to be provided by EPA. For phase II (steps 4 and 5), access to more extensive information from the NHEXAS databases (e.g., activity patterns and household attributes).
Feasibility (of analyses with current NHEXAS databases):	The study is straightforward and feasible, depending only on on-time availability of NHEXAS data for Phases I and II (as identified in the Data Needs).

Project Name:	M-15 (cont'd). Comparison of NHEXAS Findings with Cumulative Exposure Project Estimates for Ambient Air Levels and Exposures for Selected VOCs and Metals

Approximate Project Time Table and Level of Effort

Time Table:	Duration		Research Outputs
	Month	0	(1) Initiate project
	Month	12	(2) Report summarizing evaluation of the relevance of the CEP estimates for exposure assessments
	Month	24	(3) Final outputs: • Evaluation of methodologies for screening exposure assessments for airborne contaminants • Specific recommendations for improving screening modeling methodologies and data collection approaches • Peer-reviewed manuscript(s)
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	10	24	Principal investigator
	50	24	Senior-level staff ("associate")
	100	24	Junior-level staff ("assistant", technician), students
			Other (describe):

[*] Duration = approximate time (in months) needed, from start of project, to complete each step.

NOTES: This is a two-phase project (Phase I - Year 1; Phase II - Year 2). Critical results evaluating the relevance of CEP estimates will become available from Phase I, whereas Phase II will focus on more exploratory aspects of the problem, leading to recommendations for methodological improvements in screening exposure assessments.

Project Name:	**M-16. Compare Pre-NHEXAS Model Results with NHEXAS Measurements**
Short Project Description:	Compare pre-NHEXAS model results for benzene, lead, and chlorpyrifos with NHEXAS measurements. Update pre-NHEXAS models with information from the measurement data.
Goal/Objective:	Assess validity of pre-NHEXAS models by comparing with measurements. Improve these models based on data to better predict exposures.
Significance of Project:	If models and data compare well, this provides a validated model for use in predicting human exposures to these pollutants. This then can be applied to populations outside of the NHEXAS study region. Differences between measured and modeled results can be used to improve model predictions and provide information on limitations in the use of disparate studies. Overall, this comparison will provide confidence in using models to estimate multimedia exposures.
Suggested Approach:	(1) Compare environmental concentrations as predicted from pre-NHEXAS benzene, lead, and chlorpyrifos models with corresponding measurements, with special attention to high-end concentrations. (2) Extend pre-NHEXAS models to go from exposure to dose and compare NHEXAS biomarker measurements to this version with special attention to high-end measurements. (3) Examine different parameters to determine possible reasons for discrepancies between models and measurements. This should include comparison of measured and modeled time/activity diaries and concentrations in air, food, water, and other media. In addition, algorithms for calculation should also be examined. (4) Determine if model predicts better/worse for a certain population subgroup, based on location, age, race, sex or other factors. (5) Improve model estimates based on results of tasks 1 through 4.
Data or Input Needs:	Questionnaire and time/activity data, environmental concentration data, and analyte concentrations.
Feasibility (of analyses with current NHEXAS databases):	Pre-NHEXAS model code, documentation, and their results should be made available. Questionnaire data and concentration data that correspond to the pre-NHEXAS models will be available.

Approximate Project Time Table and Level of Effort

Time Table:	Duration*		Research Outputs
	Month	0	(1) Initiate project
	Month	2	(2) Compare environmental concentrations from measured and modeled results
	Month	4	(3) Extend exposure model to dose and compare with urine/blood concentrations
	Month	10	(4) Determine which inputs/algorithms/population subgroups are responsible for discrepancies between model and measurements
	Month	14	(5) Improve model based on results
	Month	18	(6) Final outputs: • Report on comparison between measured and modeled data • Improve model based on results

Approximate Level of Effort:	% Time	Months	Type of Expertise Needed
	15	18	Principal investigator
	35	18	Senior-level staff (“associate”)
	25	10	Junior-level staff (“assistant”, technician), students
			Other (describe):

* Duration = approximate time (in months) needed, from start of project, to complete each step.

Project Name:	**M-17. Construction of an Empirical Multimedia/Multipathway Exposure Distribution Model Including Temporal Variability Based on NHEXAS Data**
Short Project Description:	The NHEXAS study collects data that can be used for the development of multimedia/multipathway exposure models and also can incorporate temporal variability in exposure factor measurements. Pre-NHEXAS models were based on data from studies that often were limited in scope to single media/single pathway. Using the NHEXAS data, the pre-NHEXAS models can be extended to include multimedia/multipathway correlation between variables, both between and within individuals. This project examines the issues involved in constructing this type of model based on the data available in the NHEXAS study.
Goal/Objective:	(1) Determine limitations of NHEXAS study design in construction of empirical multimedia/multipathway exposure distributions that include temporal variability. (2) Construct empirical multimedia/multipathway exposure distribution model, including temporal variability, using NHEXAS data to the extent possible. (3) Examine issues in constructing empirical models involving temporal variability, including development of methodology for estimating multivariate distributions.
Significance of Project:	Project would extend empirical exposure distribution models to include temporal variability in individual exposure measures and development of multivariate joint and conditional distributions for use in empirical exposure distribution models. It also will highlight the limitations in the NHEXAS study design for construction of such models and provide information to improve future multimedia/multipathway exposure studies.
Suggested Approach:	(1) Use of NHEXAS Maryland data. (2) Assessment of data for use in development of multivariate exposure factor distributions. (3) Extension of pre-NHEXAS model framework to include multivariate distributions. (4) Estimation of parameters for empirical model exposure factor distributions.
Data or Input Needs:	NHEXAS study data. Pre-NHEXAS exposure models.
Feasibility (of analyses with current NHEXAS databases):	No feasibility issues beyond data and input needs.

Project Name:	**M-17 (cont'd). Construction of an Empirical Multimedia/Multipathway Exposure Distribution Model Including Temporal Variability Based on NHEXAS Data**		
	Approximate Project Time Table and Level of Effort		
Time Table:	**Duration***		**Research Outputs**
	Month	0	(1) Initiate project
	Month	2	(2) Collection and familiarity with database
	Month	9	(3) Development of methodologies for multivariate distributions
	Month	12	(4) Estimation of distribution parameters from NHEXAS data
	Month	12	(5) Development of framework for empirical distribution model
	Month	15	(6) Running and analysis of model
	Month	15	(7) Multimedia/multipathway exposure distribution model, including temporal variability
	Month	15	(8) Empirical multivariate distributions and associated uncertainties based on NHEXAS data that can be used by other modelers
	Month	20	(9) Report assessing results of model analysis
Approximate Level of Effort:	% Time	Months	**Type of Expertise Needed**
	15	20	Principal investigator
	50	20	Senior-level staff ("associate")
	100 100	20 12	Junior-level staff ("assistant", technician), students
			Other (describe):

*Duration = approximate time (in months) needed, from start of project, to complete each step.

APPENDIX 1: LIST OF NHEXAS PAPERS IN PRESS OR IN PREPARATION

In Press Journal Articles (Special October 1999 Issue of JEAEE)

NHEXAS Arizona

- "The National Human Exposure Assessment Survey (NHEXAS) Study in Arizona—Introduction and Preliminary Results"
- "Spatial Distributions of Arsenic Exposure and Mining Communities from NHEXAS Arizona"
- "Residential Environmental Measurements in the National Human Exposure Assessment Survey (NHEXAS) Pilot Study in Arizona: Multimedia Results for Pesticides and VOCs"
- "Evaluations of Primary Metals from NHEXAS, Arizona: Methods, Distributions, and Preliminary Exposures"

NHEXAS Baltimore

- "A Longitudinal Investigation of Dietary Exposure to Selected Elements"
- "A Longitudinal Investigation of Selected Pesticide Metabolites in Urine"
- "Long-Term Average Microenvironmental Time Budgets in Maryland"

NHEXAS Region V

- "Sampling Design, Response Rates, and Nonresponse Compensation for the National Human Exposure Assessment Survey (NHEXAS) in EPA Region V"
- "National Human Exposure Assessment Survey (NHEXAS): Distributions and Associations of Lead, Arsenic, and Volatile Organic Compounds in EPA Region V"
- "Population-Based Dietary Intakes and Tap Water Concentrations for Selected Elements in the EPA Region V National Human Exposure Assessment Survey (NHEXAS)"
- "Responses to the Region V NHEXAS Time/Activity Diary"
- "Analysis of Mercury in Hair of EPA Region V Population"
- "Quantification of Children's Hand and Mouthing Activities Through a Videotaping Methodology"
- "The EL Sampler: A Press Sampler for the Quantitative Estimation of Dermal Exposure to Pesticides in House Dust"

List of Manuscripts "In Preparation" Under EPA Contracts or Cooperative Agreements

Arizona

- "Occurrence/Distributions of Pollutant Concentrations in Different Media, with Comparisons Across Media for Each Pollutant" (1999)[5]
- "Exposure Model Formulation and Validation for Pesticides using the Arizona NHEXAS Database" (1999)
- "Total Exposure Assessment Estimates and their Distributions for Pesticides" (2000)

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[5]Estimated year of completion.

- "Total Exposure Assessment: The 90th Percentile of Total Exposure to Pesticides and Their Media Components" (2000)

Baltimore

- "Pesticide Residues in Urine: Temporal and Population Variability and Associations with Activities and Diet" (1999)
- "Population and Temporal Variability Analyses of Dietary Checklist Data" (1999)
- "Pesticide Residues in Urine: Associations with Questionnaire Data and Environmental Concentrations" (2000)
- "Estimated Chlorpyrifos Exposure in U.S. EPA Region V and Arizona" (2000)

Region V

- "Analysis of Dietary and Other Exposure Pathways for Metals, with Comparisons Between Media Concentrations and Routes of Exposure" (1999)
- "Assessment of Data Quality for the EPA Region V NHEXAS Study" (2000)
- "Contribution of Activity Patterns to Personal Exposures of NHEXAS Participants"
- "Relationship of Residential Sources and Residential Conditions to Household Contaminant Levels"
- "Relationship Between Pesticide Levels in and Around the Home and Hand Rinse Measurements from Children"
- "Relationship Between Activity Pattern Data and Hand Rinse Measurements of Pesticides in Children"
- "Estimation of Pesticide Exposure from Biomarker Measurements Using Environmental and Time-Activity Data To Constrain the Solutions"

APPENDIX 2: WORKSHOP AGENDA

National Human Exposure Assessment Survey (NHEXAS) Workshop Analysis of Pilot Study Data

North Raleigh Hilton Hotel
3415 Wake Forest Road
Raleigh, N. C. 27609
(919) 872-2323
FAX (919) 876-0890

Tuesday, July 27, 1999	
8:30-8:45 a.m.	Introduction (William Steen, NERL)
8:45-9:30 a.m.	NHEXAS overview, workshop goals (Judith Graham, NERL)
Overview of the hypotheses, design, and status of data analyses for each NHEXAS pilot study:	
9:30 -10:00 a.m.	The RTI-EOSHI consortia (Andy Clayton, RTI)
10: 00-10:30 a.m.	Break
10:30-11:00 a.m.	Arizona consortia (Mary Kay O'Rourke, University of Arizona)
11:00-11:30 a.m.	Harvard/Emory consortia (Barry Ryan, Emory University)
11:30-12:00 a.m.	Discussion of break-out session objectives, assignments, and charge (Judith Graham, NERL)
12:00 a.m.-1:00 p.m.	Lunch
1:00-5:00 p.m.	Break-out sessions
5:15 p.m.	Status meeting with session chairs, rapporteurs, and workshop organizers
Wednesday, July 28, 1999	
8:30-12:00 a.m.	Break-out sessions continue—meet in designated rooms
12:00 a.m.-1:00 p.m.	Lunch
1:00 - 5:00 p.m.	Break-out sessions continue
5:15 p.m.	Status meeting with chairs, rapporteurs, and workshop organizers
Thursday, July 29, 1999	
8:30 - 11:30 a.m.	Project presentations and discussion in plenary session (group chairs and rapporteurs)
11:30 a.m.	Final plenary session: "Next Steps" (Judith Graham, NERL)
12:00 a.m.	Workshop adjourns

1:00 p.m.	Status meeting with chairs, rapporteurs, and workshop organizers

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APPENDIX 5: HANDOUTS[8]

Overview of NHEXAS Pilot Study and Summary Tables for the Data Analysis Planning Workshop

July 27 to 29, 1999
Raleigh, NC

[8]Handouts not already included elsewhere in the proceedings document.

The ultimate goal of the National Human Exposure Assessment Survey (NHEXAS) is to document status and trends of national distributions of human exposure to potentially high-risk chemicals to improve the accuracy of exposure (and risk) assessments and to evaluate whether exposure (risk) is deteriorating or improving over time with the application of risk management steps. The Phase I pilot projects, which are being discussed at this Workshop, are the beginning. Based on the scientific advances from this first phase of NHEXAS, a national exposure survey is envisioned.

Phase I of NHEXAS (hereafter referred to as just NHEXAS) is perhaps the most ambitious study ever undertaken to evaluate total human exposure to multiple chemicals on a community and regional scale. It focuses on the exposure of people to environmental pollutants during their daily lives. To accomplish this, hundreds of volunteer participants were randomly selected from several areas of the country to obtain a population-based probability sample. NHEXAS scientists measured the levels of a suite of chemicals to which participants were exposed in the air they breathe, in the foods and beverages they consume, in the water they drink, and in the soil and dust around their homes. Measurements were also made of chemicals or their metabolites in biological samples (including blood and urine) provided by the participants. Finally, participants completed questionnaires to help identify possible sources of exposure to chemicals and to characterize major activity patterns and conditions of the home environment.

In addition to improving estimates of total exposure to chemicals, NHEXAS aims to:

- Identify sub-groups of the general population that are likely to be highly exposed (at least the 75th percentile) to chemicals in their environment.
- Provide a baseline of the normal range of exposure to chemicals in the general population that can be used to compare to the results of other investigations conducted at particular sites of concern or addressing specific routes.
- Compare the results of a one-week ?snapshot” of exposure to the results obtained from multiple sampling cycles over a year.
- Evaluate and improve the accuracy of models developed to predict or diagnose exposure of people to chemicals.
- Test and evaluate different techniques and design approaches for performing multimedia, multipathway human exposure studies.

The NHEXAS pilots consist of three interrelated projects, all of which were funded as co-operative agreements and coordinated by EPA's Office of Research and Development:

1) A study of several hundred Arizona residents by the University of Arizona, Battelle Memorial Institute, and the Illinois Institute of Technology.
2) A study of several hundred residents from the states of Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin by the Research Triangle Institute and the Environmental Occupational Health Sciences Institute. In addition, a smaller-scale study focused on children's exposures to pesticides, which was conducted with the participation of the Minnesota Department of Health.
3) A study of about sixty Maryland residents by Harvard University, Emory University, Johns Hopkins University, and Westat.

Two other federal agencies - the Food and Drug Administration and the Centers for Disease Control and Prevention - are assisting EPA (under Interagency Agreements) with sample analysis. The National Institute for Standards and Technology (under an Interagency Agreement) is providing quality assurance support.

Within EPA's Office of Research and Development, scientists from the National Exposure Research Laboratory, National Center for Environmental Assessment, and the National Health and Environmental Effects Laboratory participate. The first two organizations are actively engaged in the conduct of the program by serving as project officers and principal collaborators in the research.

Sample collection began in mid-1995 and was completed for all of the projects in late 1997. Analysis of almost all of the samples was completed in early 1998. After statistical analysis and summary, initial publications will be available beginning in 1999. The Consortia will be providing their databases for the NHEXAS studies to EPA in late 1999/early 2000. We expect to make the data available on the Internet by September of 2000. The two additional studies, Minnesota Childrens Study and the Arizona Border Study will be made available on the Internet as the data becomes available, possibly late 2001 or early 2002.

The attached nine tables summarize the major design elements of NHEXAS and the target analytes/methods for metals, PAHs, pesticides, and VOCs. There were common features across the three consortia. For example, all three consortia used the same basic set of questionnaires. Within chemical classes selected by the consortia, each consortium analyzed for a basic set of chemicals. However, by utilizing three consortia, alternative and innovative variations on the theme of multimedia measurements to estimate total human exposure were possible. For example, each consortium was able to target some specific concerns or opportunities. Two of the consortia focused on measuring potential exposures of each participant once; one consortia studied fewer people but repeated the measurements several times over the year to enable estimates of temporal variability for the exposures and activities of interest.

TABLE	**CONTENTS**
1	Study Design
2	Data Analysis
3	Environmental and Biological Sampling
4	Objectives and Hypotheses
5	Questionnaires
6	Target Analytes/Methods for Metals
7	Target Analytes/Methods for PAHs
8	Target Analytes/Methods for Pesticides
9	Target Analytes/Methods for VOCs

The participants were selected through a probability sample to permit statistical inferences about the larger population later. The only exception was a special panel on children exposed to pesticides. (This was based on oversampling households reporting more frequent applications of insecticides and on a commercial listing of households with listed telephone numbers that were predicted to have age-eligible children.)

Chemicals to be analyzed by NHEXAS were chosen because they are known (or strongly suspected) to present major environmental health risks, have been found in two or more environmental media (air, water, soil, food), and have been identified as being of importance to several EPA program or regional offices or other federal agencies. Chemicals were selected only if it was feasible to collect and analyze them. The chemicals fall into three categories: (1) volatile organic compounds (VOCs), such as formaldehyde, trichloroethylene, benzene, and perchloroethylene; (2) metals, such as lead, mercury, arsenic, and cadmium.; and (3) pesticides, such as the herbicide atrazine and the insecticides chlorpyrifos, diazinon, and malathion. In some media, measurements of selected polyaromatic hydrocarbons (PAHs) were made.

SOURCES OF MORE INFORMATION

Abstracts of NHEXAS results presented at the last two annual meetings of the International Society for Exposure Analysis, along with a Special Issue of the Journal of Exposure Analysis and Environmental Epidemiology (vol.5, no.3, July-Sept., 1995) which describes all major aspects of NHEXAS, will be available for review at the Workshop.

TABLE 1. SUMMARY OF NHEXAS STUDY DESIGN

Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Overview	Population-based personal exposure measurements of metals, pesticides, & VOCs	Population-based personal exposure measurements of metals & VOCs; MN children's pesticide study included pesticides & PAHs	Investigate the relationship between short-term (1-7 day) and long-term (annual average) exposure measurements for metals & pesticides
Study Design	Probability-based sample selection using multi-stage sampling; phased data collection involving varying levels of participation in each phase	Probability-based sample selection using multi-stage sampling; phased data collection involving varying levels of participation in each phase	Probability-based sample selection using multi-stage sampling; participants must agree to participate in all phases of the study
Population Selection and Recruitment	• Representative sample of general AZ population • Divide AZ into 15 regions each containing a number of "combined census block groups" with similar populations • Of these 400-600 primary sampling units (PSUs), 50 selected and divided into area segments • 5 area segments, containing 20-30 housing units each, selected as secondary sampling units (SSUs) • All houses in each SSUs randomly listed & sequentially selected until 5 participating households obtained • Seventy seven percent of the households eligible for intensive sampling agreed to participate, of these 179 (43 %) were actually sampled due to resource constraints. Lower number of samples anlyzed by Battelle in last 3 counties due to resource constrains.	• Representative sample of EPA Region 5 (IL,IN,MI, MN,OH,WI) • Select 32 PSUs (generally counties) with probability proportional to size (PPS) based on 1990 Census - stratified by size and racial makeup - four loops through Region with random starts • Select ~24 households (HHs) per PSU (for descriptive questionnaire), and one (or zero) participant per HH, to yield ~9 participants per PSU (for monitoring) • <u>Longitudinal follow</u> up by mail for participants in the first 22 sample counties for 2 different times • <u>Incentive scale</u>, based on burden (e.g., $5 baseline questionnaire, $15 for Core monitoring, +$40 aerosol monitoring, +$75 duplicate diet+reimburse for foods); eligible for Raffle (1 ticket each for food monitoring and aerosol monitoring) • <u>Response Rates</u> (weighted) - Descriptive questionnaire ~ 72% - Baseline questionnaire ~ 74% - Visit 1 - Core monitoring ~ 80% - Optional items: 50-70% - Visit 2 - Core monitoring ~ 57% - Personal VOCs ~ 41% - Visit 3 - Core monitoring ~ 48% - Personal VOCs ~ 38%	• Representative sample includes suburban, urban, & rural groups in Baltimore and surrounding counties • Study conducted in 5 political areas in Maryland: Anne Arundel County, City of Baltimore, Baltimore County excluding the City, Queen Anne County, and Talbot County. Stratify U.S. Census block groups into 5 categories: 1. Urban, predominantly white, 2. Urban, predominantly minority; 3. Suburban, predominantly 4. Suburban, predominantly minority, and 5 rural. 5 block groups. Select 5 Census block groups from each stratum. Select 20 households from each block group. Holdholds called until 90 households recruited (9-10 per stratum). Goal to retain 50 households through to end of study • Each participant/household received full sampling and questionnaire protocol 6 times evenly spaced over one year.

TABLE 1 (cont'd). SUMMARY OF NHEXAS STUDY DESIGN

Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Number of Participants and Temporal Monitoring	• Collect baseline questionnaire data on 900-1250 households • Environmental sampling and additional questionnaires for 450 households (primary respondent, plus other interested residents) • In 179 of the 450 households, intensive & temporal sampling with re-evaluation for the same pollutants using methods with greater resolution & reliability • Questionnaire data and intensive sampling conducted on an additional 85 households along the Arizona/Mexico border using NHEXAS protocols. • Baseline questionnaire data collected in an additional 200 homes and secondary sampling conducted in approximately 50 households.	• Administer Descriptive (n=555 households) and Baseline (n=326) questionnaires • Monitor 249 participants; only 1 participant per household • Two longitudinal follow ups by mail (101 participants in first follow up and 86 participants second follow up)	• 62 randomly selected people sampled remained in the study through 6 sample cycles
Types of Data Collected	Human activity (questionnaires & diaries); environmental concentrations (air, water, soil/dust surface residues); personal exposure concentrations (air, diet); human tissues/fluids (blood, urine)	questionnaires & diaries: Personal and environmental characteristics and activities; Core monitoring: Air-VOCs (indoor/outdoor, personal), Tap Water (metals, VOCs); Aerosol Monitoring: Air(Indoor, Personal Air), House Dust, and Soil (metals); Duplicate Diet: solid foods and beverages (including drinking water), diet diary and follow-up questionnaire; Biomarkers: blood, urine, hair	Human activity (questionnaires & diaries); environmental concentrations (air, water, soil/dust surface residues); personal exposure concentrations (air, diet, residue on hands); human tissues/fluids (blood, urine)

TABLE 2. SUMMARY OF NHEXAS DATA ANALYSIS			
Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Journal Articles "In Press" (Special Issue of JEAEE)	• The NHEXAS Study in Arizona-Introduction and Preliminary Results • Spatial Distributions of Arsenic Exposure and Mining Communities from NHEXAS Arizona • Residential Environmental Measurements in the National Human Exposure Assessment Survey (NHEXAS) Pilot Study in Arizona: Multimedia Results for Pesticides and VOCs • Evaluations of Primary Metals from NHEXAS, Arizona: Methods, Distributions and Preliminary Exposures • Population Based Exposure Measurements in AZ: A Phase I Field Study in Support of the National Human Exposure Assessment Survey	• Sampling Design, Response Rates and Nonresponse Compensation for the NHEXAS in EPA Region 5 • NHEXAS: Distributions and Associations of Lead, Arsenic and Volatile Organic Compounds in EPA Region 5 • Population-based Dietary Intakes and Tap Water Concentrations for Selected Elements in the EPA Region 5 NHEXAS • Responses to the Region 5 NHEXAS Time/Activity Diary • Analysis of Mercury in Hair of EPA Region 5 Population • Quantification of Children's Hand and Mouthing Activities Through a Videotaping Methodology • The EL Sampler: A Press Sampler for the Quantitative Estimation of Dermal Exposure to Pesticides in House Dust	• A Longitudinal Investigation of Dietary Exposure to Selected Elements • A Longitudinal Investigation of Selected Pesticide Metabolites in Urine • Long-Term Average Microenvironmental Time Budgets in Maryland

TABLE 2 (cont'd). SUMMARY OF NHEXAS DATA ANALYSIS			
Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Manuscripts "In Preparation" Under EPA Contracts (estimated year of publication)	• Occurrence/Distributions of Pollutant Concentrations in Different Media, with Comparisons Across Media for each Pollutant (1999) • Exposure Model Formulation and Validation for Pesticides using the AZ NHEXAS Database (1999) • Total Exposure Assessment Estimates and their Distributions for Pesticides (2000) • Total Exposure Assessment: The 90th percentile of Total Exposure to Pesticides and their Media Components (2000)	• Analysis of Dietary and Other Exposure Pathways for Metals, with Comparisons Between Media Concentrations and Routes of Exposure (1999) • Assessment of Data Quality for the EPA Region V NHEXAS Study (2000)	• Pesticide Residues in Urine: Temporal and Population Variability and Associations with Activities and Diet (1999) • Population and Temporal Variability Analyses of Dietary Checklist Data (1999) • Pesticide Residues in Urine: Associations with Questionnaire Data and Environmental Concentrations (2000) • Estimated Chlorpyrifos Exposure in US EPA Region V and Arizona (2000)

TABLE 2 (cont'd). SUMMARY OF NHEXAS DATA ANALYSIS

Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Proposed Manuscripts	• Total Exposure Assessment for Metals (same as contract papers 2-4 for metals, including Border data & comp) • Exposure Assessment for VOCs, (including Border and comparisons) • Exposure Assessment for PM10, (including Border and comparisons) • Total Exposure Assessment for Pesticides on the Border (similar to contract papers 2-4, including comparisons with the State) • Total Exposure Assessment for Children (including Border, including secondary respondents) • Total Exposure Assessment for Hispanics (including Border, including secondary respondents) • Complete Questionnaire Analysis: stat models with exposures & biomarkers • Description of Time Activities in the population and sub-populations in relation to exposures and demo. char • Use of Portable	• Contribution of Activity Patterns to Personal Exposures of NHEXAS Participants • Relationship of Residential Sources and Residential Conditions to Household Contaminant Levels • Relationship Between Pesticide Levels in and Around the Home and Hand Rinse Measurements from Children • Relationship Between Activity Pattern Data and Hand Rinse Measurements of Pesticides in Children" • "Estimation of Pesticide Exposure from Biomarker Measurements Using Environmental and Time-Activity Data to Constrain the Solutions"	

TABLE 3. SUMMARY OF NHEXAS ENVIRONMENTAL AND BIOLOGICAL SAMPLING
(refer to Tables 6-9 for details)

Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Personal Air	1. Personal VOC passive badge sample (6-day integrated). 2. Non-occupational personal VOC passive badge. 3. Active personal pump with Teflon coated filter (18-24 hour integrated).	1. Personal VOC passive badge sample (6-day integrated). 2. Non-occupational personal VOC passive badge. 3. Active personal pump (6-day integrated).	Active personal pump sample (24-hour integrated).
Indoor Air	1. Indoor VOC passive badge sample (7-day integrated). 2. Indoor VOC active pump sample (24-hour integrated). 3. Indoor active pump sample (Two 3-day integrated, including weekend).	1. Indoor VOC passive badge sample (6-day integrated) 2. Indoor active pump sample (6-day integrated)	Indoor active pump sample (7-day integrated).
Outdoor Air	1. Outdoor VOC passive badge sample (7-day integrated). 2. Outdoor VOC active pump sample (24-hour integrated). 3. Outdoor active pump sample (7-day integrated).	1. Outdoor VOC passive badge sample (6-day integrated). 2. Outdoor active pump sample (6-day integrated).	Outdoor active pump sample (7-day integrated).
Water	Drinking water sample.	1. Drinking water samples (2). 2. Standing tap water sample.	Flushed Tap Water Sample.
House Dust	1. Vacuum Sampler (floors). 2. Surface wipes (surfaces). 3. Adhesive tape transfer (surfaces).	1. Dust wipe samples on surfaces (2). 2. Plate deposition dust sample. 3. Carpet deposition dust sample.	Vacuum Sample at Fixed Surface Area.
Soil	1. Composite sample at foundation. 2. Composite sample from yard area	Composite sample from yard area.	Composite sample from yard area.
Dermal	Dermal wipe sample.	Dermal wipe sample.	Dermal wipe sample.
Food	One-day composite of duplicate diet and beverages.	Composite of four day duplicate diet and beverage samples.	1. Composite of four day duplicate diet and beverage samples. 2. Mini-market Basket.

TABLE 3 (cont'd). SUMMARY OF NHEXAS ENVIRONMENTAL AND BIOLOGICAL SAMPLING (refer to Tables 6-9 for details)

Consortium	Arizona/Battelle	RTI/EOHSI	Harvard/Emory/Johns Hopkins
Urine	One first daily void.	Two first daily voids.	One first daily void.
Blood	Personal Air	50ml venous puncture.	50ml venous puncture.

TABLE 4. NHEXAS OBJECTIVES AND HYPOTHESES

Objective/Hypothesis	Analytical Approach	Consortia
1. TEST ADEQUACY OF INITIAL EXPOSURE ASSESSMENTS		
1a. Exposure and/or concentration distributions from the initial exposure assessment are/are not comparable to the NHEXAS Phase I results.	Weighted data analysis is used to furnish population estimates.	RTI/EOHSI UA/Bat/IIT
1b. Exposure and/or concentration data from NHEXAS Phase I field studies can/cannot be used to improve exposure assessment results.	Models used to develop initial exposure assessment will be rerun using Phase I data.	HSPH/JHU RTI/EOHSI UA/Bat/IIT
2. IDENTIFY POSSIBLE SUBPOPULATION FOR WHICH EXPOSURES ARE DIFFERENT		
2a. Biologically sensitive subpopulations have/do not have total exposures similar to those of the general population.	Questionnaire data will be used to identify subpopulations and a weighted data analysis will be used to furnish (sub)population estimates.	RTI/EOHSI UA/Bat/IIT
2b. Exposures for certain segments of the population are/are not different from those of the general population.	Questionnaire data will be used to identify segments and define the domains and a weighted data analysis will be used to furnish (sub)population estimates.	RTI/EOHSI UA/Bat/IIT
2c. Biological measurements for certain segments of the population are/are not different from those of the general population.	Questionnaire data will be used to identify segments and define the domains and a weighted data analysis will be used to furnish (sub)population estimates.	RTI/EOHSI UA/Bat/IIT
2d. Environmental media concentrations for certain segments of the population are/are not different from those of the general population.	Questionnaire data will be used to identify segments and define the domains and a weighted data analysis will be used to furnish (sub)population estimates.	RTI/EOHSI UA/Bat/IIT
3. IDENTIFY POSSIBLE CAUSES FOR DIFFERENCES IN EXPOSURE		
3a. Exposures for segments of the population reporting contact with certain sources are/are not different from the general population.	Questionnaire data will be used to identify participants that report contact with potential pollutant sources and a weighted data analysis will be used to furnish (sub)population estimates.	RTI/EOHSI UA/Bat/IIT

3b. Environmental media concentrations for segments of the of the population reporting contact with certain sources are/are not different from the general population.	Questionnaire data will be used to identify homes with potential pollutant sources and a weighted data analysis will be used to furnish (sub)population estimates	RTI/EOHSI UA/Bat/IIT

TABLE 4 (cont'd). NHEXAS OBJECTIVES AND HYPOTHESES

Objective/Hypothesis	Analytical Approach	Consortia
3c. Personal exposure measurements do/do not correlate with measures of source intensity.	Questionnaire data will be used to define measures of source intensity.	RTI/EOHSI UA/Bat/IIT
3d. Environmental media concentration measurements do/do not correlate with measures of source intensity.	Questionnaire data will be used to define measures of source intensity.	RTI/EOHSI UA/Bat/IIT
4. TEST FOR ASSOCIATIONS		
4a. Personal exposure measurements do/do not correlate with biological concentrations.	Calculate correlations (Spearman and Pearson for original and log-transformed data).	RTI/EOHSI UA/Bat/IIT HSPH/JHU
4b. Personal exposure measurements do/do not correlate with environmental media concentrations.	Calculate correlations (Spearman and Pearson for original and log-transformed data).	RTI/EOHSI UA/Bat/IIT
5. APPORTION EXPOSURES AMONG MEASURED PATHWAYS		
5a. All measured pathways contribute equally/unequally to dose.	Convert concentrations to average mass/day. Estimate population means and percentiles of these measures and compare corresponding estimates across pathways.	RTI/EOHSI UA/Bat/IIT HSPH/JHU
5b. Pathway contributions are/are not independent.	Calculate inter-pathway correlations.	RTI/EOHSI UA/Bat/IIT
6. PROVIDE DATA TO DEVELOP AND IMPROVE EXPOSURE MODELS		
6a. Individual dietary exposures estimated by combining consumption data with concentration data from the FDA Total Diet Study are/are not different from those derived from Phase I data.	Food diary data are used to provide consumption estimates. Pollutant concentrations for food items are derived from the FDA Total Diet Study and duplicate plates.	RTI/EOHSI UA/Bat/IIT HSPH/JHU
6b. Individual dietary exposures estimated using a food use diary, coupled with a mini-market basket data collection procedure are/are not comparable to those derived from a duplicate diet procedures.	Food diary data are used to provide consumption estimates. Pollutant concentrations for food items are derived from the mini-market basket survey and duplicate plates.	HSPH/JHU

TABLE 4 (cont'd). NHEXAS OBJECTIVES AND HYPOTHESES		
Objective/Hypothesis	Analytical Approach	Consortia
6c. Distributions of long-term measurements (exposures, doses, and environmental media concentrations) can/cannot be estimated directly from short-duration measurements	Extrapolate measurements to annual averages. Estimate autocorrelation functions of exposure measurements by grouping observations by months. Perform seasonal adjustments. Other statistical tests such as the multiple t-test and analysis of variance will be performed.	HSPH/JHU
6d. Questionnaire data are/are not sufficient to afford prediction of exposures experienced by a study population.	Develop regression-type prediction models. Correlate predictions with measured exposures and biological markers.	RTI/EOHSI UA/Bat/IIT HSPH/JHU
7. IMPROVE DESIGN FOR NHEXAS PHASE II AND III		
7a. Response rates are/are not sufficient to use the NHEXAS Phase I methodology in NHEXAS Phase II.	Qx data are used to define domains with potentially different response rates. Response rates are computed for each stage of participation both overall and by these domains.	RTI/EOHSI UA/Bat/IIT
7b. Respondents are/are not a biased subset of sample subjects.	For each level of participation, respondents and nonrespondents are compared based on characteristics known for all participants at the previous levels	RTI/EOHSI UA/Bat/IIT
7c. Variance- and cost-component estimates from Phase I are/are not useful for optimizing Phase II designs.	Cost- and variance-components from NHEXAS Phase I (e.g, intracluster correlation for environmental and biological measurements) will be used to determine the minimum sample allocations for Phase II.	RTI/EOHSI UA/Bat/IIT

TABLE 5 QUESTIONNAIRES USED FOR NHEXAS

All three NHEXAS Phase I Field Studies used the same set of questionnaires. They were developed by EPA in cooperation with a number of recognized experts in the collection analysis of human activity pattern data, human exposure to contaminants in air and non-air media, and environmental epidemiology. These questionnaires were developed to: 1) provide descriptive information for the households and individuals included in the NHEXAS population sample compared with the target population (e.g., Census data), 2) explain variability or predict differences in exposure/dose measurements, 3) identify the presence (and, possibly, usage patterns) for major pollutant sources in the microenvironments most frequently visited by individuals in the survey (e.g., home and work place); and 4) characterize the distributions of "exposure factors" which are needed to compare and contrast exposure estimates made in the initial assessment with those derived from the NHEXAS pilot studies.

To meet these objectives, the questionnaires are designed to elicit information about each of the following topic areas: a) demographic characteristics of household residents and of selected respondent(s), b) basic household characteristics, c) activity and lifestyle factors related to pollutant exposure for the selected respondents, d) occupational factors, e) general dietary patterns and f) information health status for use in identifying high risk subpopulations..

The NHEXAS pilot study questionnaires are organized into six modules for simplicity in administration (to minimize respondent burden and maximize participation rates at each step) and for collecting information that can be temporally related to the exposure, concentration and/or biological measurements collected in NHEXAS. The six modules are:

1) **Descriptive Questionnaire** - to enumerate individuals within a household for sampling purposes (basis for selection of sample individual), to identify general characteristics of the living quarters and occupants, and to provide a basis for assessing potential bias due to refusals in subsequent steps;
2) **Baseline Questionnaire** - to provide more detailed information on the characteristics of the sample individual and housing, and on the usual frequency of activities over a longer time frame (i.e., last month or year) relative to persistence in environmental or biological media;

3) **Technician Questionnaire** - to identify and inventory the presence of pollutant sources and document physical characteristics of the building (technician completed to minimize burden on respondents);

4) **Follow-up Questionnaire** - to provide information on relatively infrequent (e.g., less than daily) activities during the sampling period to explain variation in the sample (or differences between sub-groups) for the monitoring results;

5) **Time Diary and Activity Questionnaires** - for collecting data on detailed (daily) time and location information and activity patterns (for relatively frequent activities when recalling events over several days would be more burden on the respondent); and

6) **24-hour Dietary Diary** - for collecting information on actual daily consumption patterns from the participant for use in estimating dietary exposures. The NHEXAS Phase I Field Studies will evaluate two types of self-completed food diaries: 1) an open-ended dairy and 2) a checklist of specified food categories. The main aim of the food diaries and food sample collection is to develop a suitable protocol for NHEXAS Phase II. Another aim is to test the need for making direct dietary measurements through comparisons with assessments using existing data and approaches.

TABLE 5. QUESTIONNAIRES USED FOR NHEXAS

	Descriptive	Baseline	Follow-up	Technician	Activity
DEMOGRAPHIC					
gender	D5c	B2			
age (date of birth)	D5d	B3			
race/ hispanic origin	D5e, D5f				
education	D5g	B1			
height		B4			
weight		B5			
income		B44			
location (county, city; census tract, block)	cover	cover	cover	cover	
nearest major intersection				T5	
region, urban/rural				T6a	
distance to street				T6b	
HEALTH STATUS					
current health		B20			
specific diseases, diagnoses, ages		B21(a-w)			
medications			F6(a-e)		
pregnancy or lactation			F8		
BASIC HOUSING CHARACTERISTICS					
structure	D6				
floors				T1, T2	
rooms	D7				

TABLE 5 (cont'd). QUESTIONNAIRES USED FOR NHEXAS

	Descriptive	Baseline	Follow-up	Technician	Activity
carpeting/rugs				T3	
own/rent	D8				
farm/ranch		B22			
building age		B23			
tenure		B24			
remodeling, painting		B25			
water sources, treatment		B26(a-e)			
enclosed/attached garage		B27(a-d)			
gas-powered engines		B28	F2(d,e)		
air conditioning		B29(a-c)	F1(a-b)		
evaporative coolers (AZ only)		B30(a-f)	F1(c)		
fans			F1(d-f)		
heating fuels, system		B31, B32, B33	F1(h), F1(l)		
space heaters (kerosene and gas)		B34(a-c), B35(a-c)	F1(i,j)		
wood/coal stove		B36(a-d)	F1(g)		
wood/coal fireplace		B37(a-d)	F1(k)		
air cleaner/filter			F1(m,o)		
humidifier (ultrasonic)			F1(n)		
pesticide treatments inside/outside		B38(a-i), B39(a-g)			
pesticide treatments lawn/garden		B40(a-f)			
mothballs		B41			

TABLE 5 (cont'd). QUESTIONNAIRES USED FOR NHEXAS					
	Descriptive	**Baseline**	**Follow-up**	**Technician**	**Activity**
room deodorizers		B42			
pets		B43(a-d)			
flea/tick treatments		B43(e-f)			
open doors/windows					A26
dust level/control				T4	
exterior siding				T6c	
paint exterior/interior				T6(d,e)	
materials at entrance and in yard				T6(f), T6(i)	
drip line, roof				T6(g)	
roof type/composition				T6(h)	
foundation				T6(j)	
swimming pool, hot tub, jacuzzi				T7(a,b), T8(a,b)	
EXPOSURE ACTIVITIES					
duration of time spent inside and outside by location category					home work/school/other, or in-transit
tobacco smoking	D5h	B6(a-c), B7(a-c)			
smokeless tobacco		B7d			
time near someone who was smoking		B8(a-d)			A20, A21
smoking at home	D5i	B9(a-c)			
paint walls, furniture, cars, or other objects		B10(a)			
chemical paint strippers		B10(b)			

other paint removal		B10(c)	F2(f) sander		

TABLE 5 (cont'd). QUESTIONNAIRES USED FOR NHEXAS

	Descriptive	Baseline	Follow-up	Technician	Activity
solder pipes, electronic repairs, stained glass		B11(a)			
lead-based oil paint (pictures or jewelry)		B11(b)			
paints or solvents			F2(a)		
glues and adhesives			F2(b)		
kerosene, fuel oil			F2(c)		
mold lead		B11(c)			
metal working/welding			F3(g)		
pump gas					A1
spill gas on skin					A2
enclosed garage with parked car			F5(a-c)		A3
contact with soil or dirt grass or leaves					A4 A5
fireplace or wood stove					A6, A7
grilling, burning			F4(a-d)		A8
tobacco smoked in home					A9
drinking water					A14
tobacco use					A15, A16, A17
hand washing					A18
travel on roads					A19
shower, bath					A10, A11

TABLE 5 (cont'd). QUESTIONNAIRES USED FOR NHEXAS

	Descriptive	Baseline	Follow-up	Technician	Activity
swimming					A22
prepare/apply pesticides			F2(g,g1)		A12, A13
using cleaning supplies					A23
vacuum, sweep, dust			F3(a-c)		
gardening			F3(e)		
woodworking			F3(f)		
lay/sit on carpet at home					A24
time in enclosed workshop					A25
vigorous and moderate exercise					A27-A28
DIETARY AND NON-DIETARY					
non-market foods.		B12(a,b)			
non-market fish					
non-market game					
cruciferous vegetables			F9(a-d)		
grapefruit			F9(e)		
alcoholic beverages			F9(f)		
grilled, flame broiled, smoked, or blackened foods			F9(g)		
vitamins and mineral supplements			F7 (a-d)		
special diet			F10, F11		

TABLE 5 (cont'd). QUESTIONNAIRES USED FOR NHEXAS					
	Descriptive	**Baseline**	**Follow-up**	**Technician**	**Activity**
OCCUPATION					
work full- or part-time away from home	D5j	B13			
second job		B15			
time at work		B14a, B16a			diary
working at home		B14i, B16i			
business type		B14b, B16b			
job title		B14c, B16c			
activities/duties		B14d, B16d			
protective clothing		B14(e,f), B16(e,f)			
exposures to dusts, fumes, gas, or vapors	D6p	B14(g,h), B16(g,h)			
exposures to pesticides	D6o	B14(i,j), B16(i,j),			
attend classes as student		B17a			
time at school/daycare		B17b			diary
school/daycare outside the home	D5k	B18(a-b)			
other time spent outside the home	D6n				
transportation to work/school		B19			

APPENDIX 6: COPIES OF OVERHEADS