

Questions for Studies to Develop Screening Tools for Young Children at Risk for Environmentally Mediated Neurobehavioral Disorders

1. Is EPA interested in testing alternate hypotheses rather than pursuing the current approach, examination of clinical records, as described in the RFIP?

For the purposes of this study, EPA will be supporting research to expand a database on potential predictors of behavioral disorders through the examination of clinical records. Alternate hypotheses will not be tested under this study.

2. The full text announcement cites the Duke University studies but does not identify where (if any) I can get a copy of the results, especially the screening questionnaires. Can you help?

Duke studies are not cited in the RFIP. There is a reference in the RFIP to a database developed by searching records from the Duke ADHD clinic. The clinical records are not available to the EPA, nor is information regarding specific tests or questionnaires. The database, when completed, will become EPA property and will not be publically available.

3. Is this the first time that this program has been solicited competitively?

Yes.

4. Although no cost sharing is required of applicants according to the program announcement, would applicants who provided a match be scored higher in the review process?

Applicants will be evaluated and scored based strictly on the criteria listed under section V. Applications Review Information of the Request for Initial Proposal (RFIP). Cost sharing is not listed as one of the evaluation criteria.

5. Are applicants advised to contact you before applying, or only if they have questions?

Applicants should contact the US Environmental Protection Agency with specific questions.

6. Since the project is to expand work previously conducted by Duke, what access will we have to the Duke database, and what type of information has been collected there? Are there any publications from this database that we can reference when we are writing our proposal?

The database created by Duke from records collected in their ADHD clinic has not yet been delivered to EPA. There are no related publications at this time.

7. Are there areas of NC that have been identified as being higher-risk for environmental exposures for children? There was a study in Johnston County that indicated a relatively high

prevalence of ADHD, but is this a high-risk area in terms of contaminants?

EPA is not aware of studies that specifically identify certain NC geographic areas with high risk for environmental exposures.

8. While the RFIP appears to concentrate primarily on ADHD, and it is certainly possible to do early screening for ADHD, it would also be possible to do some early screening for other neurodevelopmental disorders in school, such as learning disorders or mental retardation, language delays, etc. in younger children. Early identification of these children before they reach school age would definitely assist in early intervention and hopefully improved outcomes. This is certainly something we could add to the study, unless the funding agency would like to focus solely on ADHD.

ADHD is the primary focus of this research. Other neurodevelopmental disorders are of interest in addition (but, not in place of ADHD).

9. What is the mechanism for monitoring the children's body load of various chemicals and metals? Is this something we would have to do ourselves, or is this part of the cooperative agreement that you all would do this? Is there a specific list of chemicals and metals that you are examining?

The current project does not include biological monitoring.

10. Will it be of interest to Duke University researchers that we have developed a predictive indicator of exposure to heavy metals that would permit screening of young children to develop interventions of damaging environmental factors?

Exposure to heavy metals is beyond the scope of the current EPA request for proposals. We do not know what would be of interest to Duke University researchers.

11. Is our understanding that the total of \$120,000 for three years is direct and indirect cost such that our research budget will be approximately \$26,000/ year for three years?

The total budget is \$120,000 for three years. The exact research budget will be determined by an institution's policy on overhead costs.

12. Can special tissue samples be obtained retrospectively from the study group?

EPA has no access to the study group.

13. What is the SES, age, gender, ethnicity, demographic data of the study population?

EPA does not have this information.

14. Will the proposed interventions be psychological/behavioral, psychiatric or pharmacological in nature?

This is not known at this time.

15. What are the psychometric or behavioral criteria of ADHD used in classification of the subjects? Are the ADHD subjects subclassified into more than 2 types or is there sufficient data or interest to subclassify beyond the two (ADD & HD) types?

This information is not currently available to EPA.

16. Have the subjects been tested by functional MRI or PET or other imaging techniques?

EPA does not have any information on this topic.

17. Are there genetic or genotype data on these subjects?

Not that EPA is aware of.

18. Are there birthing data, alcohol use, life course data available for the moms and subjects?

EPA does not have such information at this time.

19. Is this an extension of research done at Duke that is likely to be restricted to that sample, and setting (essentially by those researchers)?

No, the goal of this project is to extend the database beyond the initial sample.

20. May we have access to the previous Duke research cited in the Request for Initial Proposal?

EPA is not in possession of the data collected by Duke University researchers at this time.

21. Does it seem feasible for this study to use records we would have available here which

would include children identified for school services based on ADHD-our entire student population is + 96,000 ?

EPA has no way to determine the feasibility of this approach based on the information provided.