

TOXICITY OF LEAD IN CHILDREN TRIAL: CLINICAL CENTER

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RFP AVAILABLE: NIH-ES-92-31

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National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences seeks approximately three Clinical Centers for a clinical trial, the Toxicity of Lead in Children Trial. The objective of the trial is to test the use of the drug succimer in preventing lead-induced developmental delay. Children eligible for the trial will be about two years old and will be followed until they are at least four. The trial will be double blind to the extent possible. The target lead levels will be between about 20  $\mu\text{g/dl}$  to 45  $\mu\text{g/dl}$ . All children thought to be eligible will be treated for iron deficiency, be given vitamin and mineral supplementation, and have dust control measures instituted in their homes.

It is anticipated that there will be three Clinical Centers and one Coordinating Center (Request for Proposals NIH-ES-92-32). Clinical Centers will cooperate with the Coordinating Center and the other two Clinical Centers in developing, testing, and refining the overall program and in writing the final protocol, Manual of Operations, and training materials before recruitment commences. Each Clinical Center will be responsible for screening, recruitment, randomization, treatment, developmental testing, and follow-up of study subjects. Optimally, no more than three Clinical Centers will randomize to drug or placebo on the order of 1000 total children during a 1-year enrollment and treatment phase.

The Government estimates that an average of five professional FTEs, two technical FTEs, one clerical FTE, and one other FTE will be required on an annual basis per Clinical Center. The estimated period of performance is five years. Release date of the RFP will be on or about August 6, 1992 with proposals due November 4, 1992. All responsible sources may submit a proposal that will be considered by the agency.

Requests for the RFP must reference RFP NIH-ES-92-31 and must be forwarded to:

National Institute of Environmental Health Sciences  
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