

TOXICITY OF LEAD IN CHILDREN TRIAL: COORDINATING CENTER

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RFP AVAILABLE: NIH-ES-92-32

P.T. 34; K.W. 0755015, 1007009, 0755018

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences seeks a Coordinating Center 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.

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It is anticipated that there will be three Clinical Centers (Request for Proposals NIH-ES-92-31) and one Coordinating Center. The Coordinating Center will cooperate with the three 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. The Coordinating Center will plan randomization 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. The estimated period of performance is six years. Release of the RFP will be on or about August 6 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-92-32 and must be forwarded to:

National Institute of Environmental Health Sciences
Contracts and Procurement Management Branch
ATTN: Thomas M. Hardee, Contracting Officer
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-7893
FAX: (919) 541-2712