

RFP-NIH-NIAID-DAIT-04-44
Amendment #1

“REGULATORY MANAGEMENT CENTER - DAIT”

Amendment Issue Date: December 17, 2003

Proposal Due Date/Time: February 17, 2004, at 3:00 PM., EST

Issued By: Barbara A. Shadrick
Senior Contracting Officer
RRCB/CMP/DEA/NIAID/NIH/DHHS
6700-B Rockledge Drive, Room 2230,
Bethesda, Maryland 20892-7612

Points of Contact: dreeves@niaid.nih.gov
Dominic Reeves, Contract Specialist

Please also cc:
leaton@niaid.nih.gov
Lois Eaton, Contract Specialist

Applicants/Offerors must acknowledge receipt of this Amendment # 1, for each posting, on each copy of the application/proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your application/proposal.

The hour and date specified for receipt of applications/proposals HAS NOT been extended.

The Division of Allergy, Immunology and Transplantation (DAIT) of the National Institute of Allergy and Infectious Diseases (NIAID), plans, sponsors, and directs national and international research programs in basic immunology, asthma, and allergic and immunologic diseases. Through these programs, DAIT supported investigators conduct clinical investigations into the causes, diagnosis, prevention and treatment of a broad range of immunologic disorders.

The purpose of the four solicitations: RFP NIH-NIAID-DAIT-04-43; RFP NIH-NIAID-DAIT-04-44; RFP NIH-NIAID-DAIT-04-45; and RFP NIH-NIAID-DAIT-04-46, is to establish the necessary infrastructure to support the following clinical research programs, including the Immune Tolerance Network (ITN); the Autoimmunity Centers of Excellence (ACEs); the Cooperative Clinical Trials in Pediatric Transplantation (CCTPT); the Inner City Asthma Consortium (ICAC); and the Stem Cell Transplantation Consortium (SCTC).

RFP- RFP NIH-NIAID-DAIT-04-43 will establish the Technical and Administrative Support Center for DAIT clinical research programs. This contract will provide both technical and administrative support directly to DAIT for all DAIT clinical research programs. The potential contractor will work primarily with DAIT staff and any interactions with the other contractors will be coordinated by DAIT.

RFP NIH-NIAID-DAIT-04-44 will establish the DAIT Regulatory Support Center and will provide all regulatory support services to the ITN, as well as assistance with some of the other DAIT clinical research programs. The contractor will interact with DAIT staff and investigators in the ITN.

RFP NIH-NIAID-DAIT-04-45 will establish the DAIT Clinical Product Distribution Center and will be responsible for obtaining, storing and delivering investigations agents used in clinical trials performed in the ITN. The contractor will primarily interact with DAIT staff the ITN and its investigators.

RFP NIH-NIAID-DAIT-04-46 will establish the DAIT Clinical Site Monitoring Group and will be responsible for monitoring the performance of clinical sites participating in clinical trials conducted in the ITN. The contractor will primarily interact with DAIT staff, the ITN and its investigators and the ITN data center.