

Request for Proposals Under RFP: NIDCR-DR-04-15

Clinical Trial of Topical Thalidomide for Aphthous Stomatitis in Patients with HIV/AIDS

Request for Proposals: NIDCR-DR-04-15

Amendment Number: 02 (Two)

Issue Date: December 18, 2003

Issued by: Rick Phillips, Contract Specialist
NIH/NHLBI, Contracts Operations Branch
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

Telephone Number: 301-402-6462

FAX Number: 301-480-3432

E-Mail: phillipr@nhlbi.nih.gov

Purchase Authority: 42USC201, Public Health Service Act of 1944, as amended

Small Business Set-Aside: Yes; NAICS 541710

Just In Time: Yes

Proposal Intent Due Date: December 31, 2003

Proposal Due Date: **January 23, 2004, 4:00 PM (Eastern Standard Time)**
*******Changed in Amendment 1*******

The purpose of this amendment to RFP NIDCR-DR-04-15, is to (1) revise the Request for Proposals and (2) provide NHLBI responses to questions from potential offerors.

(1) On page 7, the last sentence of bullet 1 of paragraph 1 of Task 3 is revised to read “Identify problems in adhering to the details of the protocol and help solve these problems promptly.”

(2) The following questions and responses are provided as clarification for RFP: NIDCR-DR-04-15:

Question a. How often and how long is drug applied by the subject? Please clarify the total treatment duration.

Response: The drug will be applied 4 times per day for up to 4 weeks or until ulcer is healed, which ever occurs earliest.

Question b. Will the NIH Pharmacy directly ship the study drug to each clinical center?

Response: The NIH Pharmacy will ship drugs directly to the clinical sites based on the randomization given for a particular patient by the coordinating center.