



REQUEST FOR PROPOSAL AMENDMENT NO. 01

(RFP) NO.: NIMH-03-DM-0003

TITLE: **“Treatment Units for Research on Neurocognition and Schizophrenia (TURNS)”**

DATE RFP ISSUED: April 15, 2003

DATE AMENDMENT NO. 01 ISSUED: May 5, 2003

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PROPOSAL RECEIPT DATE: **The due date for receipt of this proposal is hereby CHANGED from May 30, 2003 to a revised date of August 15, 2003.**

PROPOSALS DUE: **August 15, 2003, no later than 1:30 PM local prevailing time**

To all Offerors: The purpose of this amendment is to respond to questions from offerors and extend the due date for receipt of proposals until August 15, 2003.

Note: The anticipated time frame for award which was referenced on the first page of the solicitation (second paragraph) has been changed. The revised sentence should read: "It is expected that one cost-reimbursement contract will be awarded during the summer of 2004 with a base period of four (4) years"

Questions and Answers:

1. We would like to submit our proposal as joint PI's. Is this allowable? If so, is there a preferred format, e.g. PI/Co-PI?

As stated in the solicitation, under G. TECHNICAL PROPOSAL INSTRUCTIONS, "It is anticipated that a single contract will be issued for the project as a whole, and the primary contractor shall operate as the Coordinating Center and issue subcontracts to each TURNS." If you elect to propose joint PIs, a single site must be identified as "the leader among peers" and Coordinating Center.

2. Why was no budget figure provided in the solicitation?

Technical considerations are paramount in making an award decision. See attachment 3, item II. RELATIVE IMPORTANCE OF TECHNICAL AND COST FACTORS. However, cost reasonableness is an important factor in selecting the contractor, which makes it imperative that offerors propose a cost efficient budget which supports their unique technical approach.

3. Regarding the ongoing MATRICS study, are any cognitive measures showing favor at this time?

It is too early to determine which cognitive measures may emerge from the MATRICS study. It is anticipated that the MATRICS cognitive measure will be completed (along with psychometric and validation studies) around January 2005. We anticipate that the measure should be available by the time the first study is initiated.

4. Are any candidate compounds or drug classes preferred (from the MATRICS Study or elsewhere)?

As part of the MATRICS contract, a database of lead compounds will be developed based on interviews with industry and academic scientists. A conference scheduled for June 2003 will review promising molecular targets for therapeutics development.

5. Are you interested in actual plans at this point, or "thought experiments" now, and more formal plans later?

Since the cognition measure and lead compounds have not yet been specified, the response should anticipate these deliverables from the current MATRICS program.

6. Is it feasible to integrate neuroimaging or molecular approaches into the PK/PD studies?

Integrating neuroimaging and/or molecular approaches into the PK/PD studies and/or therapeutic studies may be possible, but would likely require independent funding or applications for funding from government, industry or foundation sources as it is not intended that this type of work will be funded under this contract.

7. May we enlist the collaboration of other entities, such as VA centers or pharmaceutical companies?

Collaborations to allow cost-effective accomplishment of tasks is encouraged and fostering academic-industry collaborations is a central goal of the MATRICS program. An alliance with a single pharmaceutical company is potentially problematic insofar as achieving broad consensus about measures and methods appears to be a prerequisite for addressing regulatory concerns about cognition in schizophrenia as a clinical target for drug registration. We are hopeful that industry will nominate promising compounds for testing in the network. An alliance with more than one company involved in CNS development or other method of insuring that a range of companies with promising compounds can access the network may be required if industry is to be a partner in organizing the network per-se. Evidence that the TURNS can form collaborative relationships with industry to identify and obtain access to promising compounds should be addressed in the proposal.



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