RFP-NIH-NIAID-DAIT-07-33
Amendment #1 (Questions & Answers)

This Amendment provides questions submitted by potential offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment will be updated at least weekly to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment for additional Q&A.

"Clinical Research Products Management Center"

Amendment No.	1 (2nd Posting)
Amendment Issue Date:	May 18, 2006 (Questions 5- 10)
Proposal Due Date/Time:	June 8, 2006, at 3:00 P.M., EST (Unchanged)
Issued By:	Lawrence M. Butler Contracting Officer AIT-RCB/OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3149, Bethesda, Maryland 20892-7612
Points of Contact:	phastings@niaid.nih.gov Phil Hastings, Contracting Officer Phone: 301-496-0194 **Please also cc:** lbutler@niaid.nih.gov Lawrence M. Butler, Contracting Officer Phone: 301-496-0192

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this amendment. Failure to receive your acknowledgement of this amendment may result in the rejection of your offer. This amendment shall be acknowledged in the following manner:

- By acknowledging receipt of this amendment on each copy of the offer submitted.

THE FOLLOWING PAGES PROVIDE ANSWERS CONCERNING A NUMBER OF INQUIRIES WE HAVE RECEIVED FOR THE ABOVE NUMBERED ACQUISITION:

Description

1. The due date for proposals has been extended to Thursday, June 8, 2006 at 3:00pm EST.

2. The primary point of contact for RFP-NIH-NIAID-DAIT-07-33 is changed to:

Phil Hastings-Tickerhoff
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3. The following questions were submitted regarding RFP-NIH-NIAID-DAIT-07-33; the responses are listed below each question.

OVERALL STRUCTURE

Question 1 a. Does the 300 page limit include appendices?

The page limit refers only to the technical proposal (see cover sheet and Attachment 5, page 1 of Appendix A, Additional Proposal Instructions).

b. Should SOPs be placed in appendices? Linked to a website?

SOPs are part of the 300 page limit (see references to RFP in 1a, above). Attachment 5, Appendix A, paragraph E.1.e refers to providing examples of SOPs for laboratory capabilities; other references to SOPs in the Statement of Work (SOW, Attachment 3) refer to work to be performed by the awardee, e.g., develop and disseminate SOPs for specific work items.

BUDGET

Question 2 a. How should ongoing trial commitments be incorporated into the budget: the detailed budgets for each site in an Appendix, or just a lump sum for each trial listed in the RFP?

The RFP refers to these issues in the sections on Transition Plans. Attachment 5 (H.1.d of Appendix A) refers to a plan to establish subcontracts, consulting agreements. The SOW (Attachment 3, IX.A) states that an Initial Transition Plan, including a plan to establish subcontracts shall be submitted with 6 weeks of the contract award. Attachment 6, Appendix B, Additional Business Proposal Instructions, Section 3.2.a states that offerors should assume clinical trials in progress will be transitioned. Section 5 Budget Instructions describes a one page budget summary as well as individual budget breakdowns by research category.

TRIAL IMPLEMENTATION RESPONSIBILITIES

Question 3 a. Please confirm that the RFP requires that the ITN be responsible for Trial implementation. Does the ITN gain oversight of CRO activities or does that remain the responsibility of the NIAID? This question is based on the following statements in RFP:

i. "assign Protocol Managers to oversee the implementation and conduct of each clinical trial and to serve as the primary contact to the NIAID medical monitors, NIAID project managers, and NIAID regulatory affairs officers."

ii. Provide protocol managers to facilitate study implementation, monitor patient accrual and retention, assess compliance with protocol requirements and adherence to study timelines, and report progress to designated NIAID Project Manager.

iii. The primary role of NIAID staff will be to facilitate, but not to direct, protocol selection, development and implementation activities. NIAID staff and ongoing NIAID clinical research support contracts will provide a broad range for services to the Contractor for the design, development, implementation and analysis of Network studies.

The Network will not be responsible for oversight o current NIAID CRO contractors. Attachment 34, Appendix E NIAID-Funded Clinical Research Support Services Contracts describes contracts that the NIAID/DAIT holds to support the effort of the Network. As noted, the successful Offeror is expected to interact in order to perform functions specified within the SOW. No oversight role of these contracts by the Network is requested in the RFP.

STUDY PRODUCT DISTRIBUTION

Question 4 a. There is an inconsistency in the RFP related to Drug distribution which is correct and does the ITN oversee the contractor (Eminent)

i. FROM SOW: Ensure that all clinical sites receive the required supply of study products for clinical trial initiation and conduct, and monitor supply throughout the duration of the clinical trial. Report to the designated NIAID Project Manager any changes in requirements for study products.

ii. FROM TOC: Study Product Distribution: NIAID will:
Manage all activities related to study product distribution, tracking and retrieval and ensure that such activities are in compliance with cGCP and consistent with relevant Clinical Trial Agreements, where applicable.

The Network will not oversee the drug distribution contractor; this remains an NIAID responsibility. It is expected that the Network will assist NIAID to ensure drug availability through and exchange of information concerning on-site drug supplies and needs. Attachment 34, Appendix E NIAID-Funded Clinical Research Support Services Contracts describes the role of the NIAID/DAIT Drug Distribution Center, which provides pharmaceutical services to support the Network. The SOW section referenced above (IV.D.8) provides instruction that the Network is monitoring study product at the site level and reports to NIAID any necessary changes. The NIAID would then instruct the drug distribution contractor to address these changes

Original Point of Contact

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Question 5 Ambiguities remain in the description of clinical trial development and implementation responsibilities of the Contractor versus those of the NIAID (or NIAID's Clinical Research Support Services Contracts). Please clarify.

NIAID acknowledges that the integration of clinical trial resources to successfully conduct clinical studies is a complex endeavor and welcomes the opportunity to further address this concern. NIAID anticipates a collaborative relationship with the Contractor, NIAID support contractor expertise, and information helping to facilitate development and conduct of clinical trials.

The RFP states (Attachment 3 Statement of Work [SOW], Section IV. A.1 and A.2) the "Contractor shall provide all personnel, resources, and facilities necessary to design and conduct Phase I- IV clinical trials …" and to particularly "establish a Protocol Development Team". Additionally, "The Network staff and protocol Principal Investigator shall be responsible for overall protocol development and shall assign responsibilities … for protocol development." Furthermore the RFP lists (Attachment 3, SOW, IV. D) several additional requirements for the management and oversight of clinical trials including, for example, providing protocol managers to facilitate study implementation among other duties; providing ongoing

training to clinical site personnel; and ensuring clinical sites receive study products for initiation of studies as well as through out the study.

A description of responsibilities for both the NIAID staff and NIAID Clinical Research Support Services Contractors are outlined in Attachment 5, Appendix A Additional Technical Proposal Instructions, Section 1.D.3. Additional details are provided for the NIAID Clinical Research Support Services Contracts in Attachment 34, Appendix E. These sections note that, "The primary role of NIAID staff will be to facilitate but not to direct protocol selection, development and implementation activities". The activities of NIAID and its support contractors includes providing Regulatory Affairs support for the Network, conducting GCP training, biostatistical and clinical data management support, as well as medical and protocol management support.

The intent of NIAID is to have the responsibilities and resources of NIAID (staff and contractors) complement, as much as possible, the expertise and resources required of the Contractor and to actively work with Network investigator and protocol teams to provide them with timely information and recommendations. For example, while Network staff and investigators will be primarily responsible for protocol development and implementation including identification of study sites, NIAID project managers in collaboration with contract resources have the resources to evaluate potential study sites through a variety of different site evaluation visits. The information obtained, and NIAID recommendations that result, from such visits will be made available to the Network to guide site selections or remedial intervention steps if needed. Another example of complementary roles is the management of the study products. While study product distribution and overall study product tracking occurs through a NIAID drug distribution center contract, the Network will need to develop a mechanism to track product at the sites so that adequate supplies of study product are maintained and requests to replenish site study products can be made to the drug distribution contractor through the NIAID project manager.
Site personnel education and training are complex and is a shared responsibility as reflected in the RFP since both the Contractor and NIAID staff/contract resources have training roles. While it is noted (Attachment 3, SOW, Section IV.D.5) that the Network will provide training on protocol requirements and compliance with regulations, NIAID also has the training capacity for GCP that could, for example, occur at the time of site initiation visits or periodic monitoring visits, particularly if compliance issues are identified. NIAID would review with the Contractor which resource would be most applicable at a given time. Thus, while some redundancy of this or other resources may be evident, NIAID's intent is to apply these resources in a complementary fashion, as dictated by circumstances.

Question 6 The scope of work asks for 6 clinical trials per year for the duration of the contract. This raises several questions that I hope you can answer.

a. The description of the trials leads to an estimate of approximately 510 patients at about 25-30 sites each year. Given some average costs/patient for the type of clinical trials conducted by the ITN, we are wondering whether this scope is really envisioned. If so, the scope in terms of personnel and budget is well above what the ITN is currently spending.

The RFP calls for protocols in the clinical areas of transplantation, asthma and allergic diseases as well as autoimmune diseases. We anticipate (Appendix B, Sec 3.2.b) 2 clinical trials per year in each clinical area – one is expected to be smaller and limited to 2 years duration and the other is anticipated to be larger and on average have approximately 150 study participants. While we anticipated that multiple sites will be used for each study, we also anticipate the majority use of Clinical Trial Units (Attachment 3, Statement of Work, IV.C.1) that have capacity to conduct multiple clinical studies and should result in significant efficiencies in the cost of the studies. If the studies that are limited to 2 years prove to take longer than this, then fewer studies in subsequent years would be expected.

b. Is it the expectation of NIAID that the ITN conduct trials in partnership with industry, where the industry partner would be expected to cover a substantial portion (e.g., 50%) of the trial costs? Would this be the only trials that the ITN would be expected to conduct?

We do anticipate that the successful offeror will have numerous collaborations with industry partners for clinical and laboratory based studies. Some of these collaborations may result in additional financial support beyond the provision of investigational agents but we do not expect the offeror to anticipate the routine support of trial costs as the question suggests.

Question 7 The RFP also suggests that this activity will exist throughout the contract without a tapering off period. Based on our experience that the average trial is 3-4 years, this would mean that in years 6 and 7 we would be starting a number of trials with no obvious exit strategy. Is this what the RFP really meant to say? Is it expected that the clinical trial obligations remaining at the end of the current contract are paid out of the successor contract?

We expect that with additional emphasis on shorter study duration, as noted above, that the length of the average trial will drop. The RFP does require the development of a Final Transition plan (Attachment 3, Statement of Work, IX.B) which will be established at the end of the contract period. However, as in the current RFP (Appendix B, Sec 3.2.a), we anticipate that there will be studies completed over the next contract period should the government choose to recompete the Network.

Question 8 Is it the anticipation of NIAID that the allocation of funds between infrastructure, research and clinical trial activity is similar to the current contract? There were no percentages suggested as there were last time around.

The construction of the current RFP is quite different than the initial solicitation mirroring the significant changes in the Network description. It is anticipated that the offeror in responding to the Statement of Work will allocate funds as needed to address the Strategic Plan and Research Agenda proposed by the investigators.

Question 9 Under the Expansion Options, 2 new 1-yr mechanistic assay studies are called for. It is not clear, whether these assay studies are meant to occur in conjunction with non-ITN supported clinical trials, Consortia studies to evaluate new assays, or Core research and development studies to scale up research assays to become more suitable for high throughput? The one year time frame seems to rule out the clinical trial scenario, but we are not sure what was envisioned in this section.

This section of the Business Proposal Instructions (Appendix B, Section 4.4) was intended to give the offeror flexibility in how to choose to respond to these activities. You may propose how you choose to utilize these mechanistic study options.

Question 10 In the instructions for submission of the application it states that no links to websites are allowed that may provide additional information to the reviewers. Given that there are over 100 key contributors to the ITN and that we need to provide SOPs (most of them 5 or more pages in length) it is not clear how we can stay within the 300 page limit specified in the RFP for the technical proposal and yet provide all the information requested. We had planned to create one dedicated website for reviewers where they could get all the relevant information that could not be included in the proposal. Would it be possible to modify the RFP to allow offerors to create such a website for the reviewers?

We appreciate the opportunity to reassess this question. We agree that the number of biosketches that are needed could significantly impact the page limit. Therefore, we have decided to exclude biosketches from the 300 page limit for the technical proposal. There will be no page limit for the biosketches. As noted in Amendment 1 use of a website is not permitted, and the RFP only requests examples of SOPs.