

**RFP-NIH-NIAID-DAIT-04-46**  
**Amendment #2 (Questions & Answers)**

This Amendment provides questions submitted by potential applicants/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 #2 for additional Q&A.**

**“Immune Tolerance Network – Clinical Site Monitoring Group”**

**Amendment No.:** 2 (2<sup>nd</sup> Posting)  
**Amendment Issue Date:** January 7, 2004 (Questions 1 – 6)  
February 5, 2004 (Questions 7 – 8)  
**Proposal Due Date/Time:** February 24, 2004, at 3:00 P.M., EST  
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Applicants/Offerors must acknowledge receipt of this **Amendment #2, 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.

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The following answers are provided concerning a number of inquiries we have received for the above numbered acquisition:

**Question 1** Do you anticipate that the labor requirements will ramp up and down depending on work requirements?

*The labor requirements will be variable depending on the number of studies open to enrollment and the number of sites participating in each trial. In the SOW, we indicated that at any time, the ITN may have 15-20 ongoing studies and the number of sites for each study will range from 1-10, with an average of 1-3 sites for each study. The number of studies is a maximum and could be lower depending upon the types of trials.*

**Question 2** Are appendices considered part of the technical proposal?

*Yes. Appendices are considered part of the technical proposal and are included within the technical proposals page limit of not-to-exceed 100 pages.*

**Question 3** Is there a specific travel policy that is applicable to this RFP?

***The regulations specified in Federal Acquisition Regulation (FAR) 31.205-46—Travel Costs are applicable to this solicitation.***

**Question 4** The FTE's and project hours do not match—which is correct?

***The estimated labor hours per year stated under the Estimate of Effort in Section L of the RFP is 19,136. By dividing those estimated hours by a single FTE's 2080 work hours per year, the Government estimates the effort to be approximately 9.2 total FTE's. This figure was incorrectly approximated at 9.1 in the original solicitation. The Estimate of Effort information is furnished for the offeror's information only and not to be considered restrictive for proposal purposes.***

**Question 5** Does the annual report count against the page count for the business proposal?

***Yes. The annual financial report is included in the business proposal's page limit.***

**Question 6** Do the Repts and Certs count against the page count for the business proposal?

***No. The Repts and Certs are not included within the Business Proposal's page limit.***

**Question 7** In relation to the performance of Item No. 1 of Task E of the Statement of Work, what current program does the statistical center utilize and what types of files are involved in the transfer?

***Currently, the Statistical Coordinating Center uses Oracle Clinical to store study data and converts all data sets into SAS data sets prior to doing interim analysis and final analysis.***

**Question 8** Would the monitors be accessing a web-based program (such as Study Manager) to upload this information, or would it be transferred via a SAS or Oracle-based file that would be generated from the actual clinical database that houses the subject data?

***Currently, there is no interface for external groups to access (unless special software is purchased and installed). However, the Statistical Coordinating Center can extract data to a PDF file or an excel file and post to the ITN portal system for outside entry. The project does not currently utilize the Study Manager program.***