

**Amendment #4
to RFP-NIH-NIAID-DAIDS-01-15**

"Clinical Site Operations and Monitoring Project"

Amendment to Solicitation No.: [NIH-NIAID-DAIDS-01-15](#)

Amendment No.: Four (4)

Amendment Date: October 3, 2000

RFP Issue Date: *May 8, 2000 (Unchanged)*

Issued By: Barbara A. Shadrick
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Name and Address of Offeror: To All Offerors

The above referenced solicitation is hereby amended as follows to respond to questions submitted by recipients of this RFP:

- 1) REFERENCE: III. NOTES TO OFFERORS (PAGE 5) #6 AND #9. WILL CONTRACTOR BE RESPONSIBLE FOR PREPARING AND SUBMITTING IND SAFETY REPORTS (EXPEDITED REPORTS) TO FDA AND TO OTHER PARTICIPATING AGENCIES AS PER LOCAL COUNTRY REQUIREMENTS?

It is anticipated that the majority of the studies supported by the Contractor will be INDs held by individual investigators. Therefore, the likelihood of the Contractor preparing IND safety reports to an FDA IND file will be rare.

- 2) WILL THE CONTRACTOR BE RESPONSIBLE FOR REPORTING LOCAL NON-US ORIGIN SERIOUS ADVERSE EVENTS TO THE APPLICABLE LOCAL AGENCY(IES)?

It is anticipated that the contractor will not be responsible for reporting local non-US origin serious adverse events to the applicable local agency(ies).

- 3) REFERENCE: III. NOTES TO OFFERORS (PAGE 5) #9. DOES THE 50 AES PER YEAR REFERENCED IN RFP REPRESENT 50 IND SAFETY REPORTS (EXPEDITED REPORTS) OR 50 SERIOUS ADVERSE EVENTS (ENCOMPASSING BOTH EXPEDITED AND NON-EXPEDITED SERIOUS ADVERSE EVENT REPORTS)?

Please refer to D.3 and note to offeror. The reference to 50 AEs represents 50 serious adverse events submitted to DAIDS medical and regulatory staff from the DAIDS grantee. This is further elaborated on in SOW D.4 and the referenced web site for the “NIAID Policy on the Monitoring of Clinical Trials and Studies”.

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- Offerors must acknowledge receipt of this Amendment #4, on each copy of the proposal submitted.
- Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.

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