OMB No. 0990-0115

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
001	See block 16C		

6. ISSUED BY CODE

National Heart, Lung, & Blood Institute, NIH
Rockledge II Building, Room 6016
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

7. ADMINISTERED BY *(If other than Item 6)* CODE

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

Recipients of RFP NHLBI-HR-05-04
Clinical Centers for a Clinical Research Network for the Treatment of Acute Lung Injury and Acute Respiratory Distress Syndrome

CODE FACILITY CODE

(✓)	9A. AMENDMENT OF SOLICITATION NO.	10A. MODIFICATION OF CONTRACT/ORDER NO.
✓	NHLBI-HR-05-04	
	9B. DATED *(SEE ITEM 13)*	10B. DATED *(SEE ITEM 13)*
	7/2/04	

11. THIS ITEM APPLIES TO AMENDMENTS OF SOLICITATIONS

☑ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☑ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning 2 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(✓)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not, ☐ is required to sign this document and return ___ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

This is to amend SECTION C, DESCRIPTION OF REQUIREMENT of the RFP, update provisions of the RFP, and provide information in a question and answer format based on inquiries from potential offerors.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		Pamela S. Lew, Contracting Officer HLVD Contracts Section, COB, DEA, NHLBI	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
		BY /S/	8/13/04
(Signature of person authorized to sign.)		*(Signature of Contracting Officer)*	

SECTION C, DESCRIPTION OF REQUIREMENT, d. Offerors must address, Item 3 is amended to read as follows:

3. Propose TWO clinical research trials in patients with or at risk for ALI/ARDS. Keeping in mind the limitation of 1650 patients to be enrolled over the five and one-half year enrollment period, offerors should propose innovative approaches for study designs which will allow for the conduct of 3-4 trials. Phase II and/or Phase III clinical studies are appropriate to show potential to prevent, treat, or improve the outcome of patients with lung injury. Exploratory, safety (Phase I), or purely pathogenic studies are not appropriate for the network. Factorial studies or other efficient or novel designs which will make maximum use of the 1650 patients should also be considered. Each research protocol is not to exceed 6 single-sided pages as part of the technical proposal and should include the hypotheses or questions to be addressed, background and rationale of the proposed study, preliminary data, patient groups to be studied including women and minorities, number of patients per group, experimental approaches and methods (including power and statistical analysis) to be employed, and the significance of the anticipated results. As an appendix to the cost proposal, provide a budget that shows labor, patient care, and other costs for each clinical trial. These costs can be detailed using the spread sheet in SECTION J of the RFP, adjusted for each proposed clinical trial. For example, core level of effort would need to be replaced with estimated level of effort for each trial.

SECTION I - CONTRACT CLAUSES: Additional Contract Clauses, I.3.a., Item 34: FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (June 2003) is deleted in its entirety.

SECTION M - EVALUATION FACTORS FOR AWARD: Item 4. PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS is deleted in its entirety.

The following questions and answers are provided based on inquiries from potential offerors:

1. QUESTION: Would pathogenesis studies be responsive to the RFP?

   ANSWER: No. Studies must be designed to prevent, treat, or improve the outcome of patients with or at risk for ALI/ARDS, and must not be purely descriptive of the natural history of the syndrome.

2. QUESTION: Can studies of patients with closely related critical illnesses, or subgroups of patients with ALI/ARDS, be proposed?

   ANSWER: Yes. Studies that have the potential to improve outcomes of patients with lung injury are acceptable. The scientific merit and feasibility of proposed studies will be evaluated by a peer review panel.

3. QUESTION: Can a principal investigator of a clinical center assist the clinical coordinating center in developing approaches to data collection?

   ANSWER: Yes, as long as there is no possibility of a breach of confidentiality of clinical data collected by the clinical coordinating center. The feasibility and merit of such a relationship will be evaluated by a peer review panel.

4. QUESTION: Can offerors develop relationships with commercial institutions to provide resources for the network?

ANSWER: Yes. Offerors should include in their proposals letters of commitment from institutions that have expressed an interest in providing resources for the study. However, the NHLBI would negotiate any formal agreements with these institutions.

5. QUESTION: Must each clinical center be able to document the ability to recruit 51 percent women and 25 percent minorities?

ANSWER: No. SECTION C: DESCRIPTION OF REQUIREMENT, c. Detailed Description of Technical Requirements states, "Funding decisions may be made with the objective of obtaining a trial-wide patient mix which includes 51 percent women and 25 percent minorities." Offerors must demonstrate the ability to recruit women and minorities based on past experience, and/or identify what efforts will be made toward achieving this mix. Final award selection will be made by NHLBI aimed at achieving this mix.