AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID NO.	PAGE OF PAGES
	1 of 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(if applicable)*
002	Jan 17, 2006		

6. ISSUED BY — CODE

National Institutes of Health
National Heart, Lung, and Blood Institute
Rockledge II, Room 6114
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–06–08
Long-term Oxygen Treatment Trial (LOTT) – Data Coordinating Center (DCC)

CODE — FACILITY CODE

(✓)	9A. AMENDMENT OF SOLICITATION NO.	9B. DATED *(SEE ITEM 13)*	10A. MODIFICATION OF CONTRACT/ORDER NO.	10B. DATED *(SEE ITEM 13)*
✓	NHLBI–HR–06–08	January 17, 2006		

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.

Offerors 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 *(if required)*

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 data, 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.)*

Recent inquiries are addressed on Page 2

Note: A picture of the Contracting Officer's signature is omitted from Block 16B. of this amendment to reduce the file size.

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)*
	Joanne Deshler Contracting Officer, HLVD Branch

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign.)		BY /s/ *(Signature of Contracting Officer)*	1/17/2006

1. ***The first sentence of item #14 on page 11 is incomplete. Words are missing after the phrase 'for the'. The information in this sentence may or may not be important but clarification would be helpful.***

   Item 14 should read:

   Final Limited Access Data Set: The contractor shall provide a final limited access data set with full documentation. The data set shall include all phenotypic and outcome data for all subjects with reductions and redactions only as needed to ensure subject privacy. The data set and documentation shall be prepared in accordance with the NHLBI Limited Access Data Clause: http://www.nhlbi.nih.gov/resources/deca/policy.htm.

2. ***On page 11 (#7 and #8), NHLBI requests a CD or DVD copy of all pages of the Study and Public websites. Is NHLBI requesting all pages of the final websites at the time of delivery or all pages, including copies of old pages that have been updated during the study be delivered?***

   The receipt date for deliverable 7 and 8 is March 19, 2007. This date was chosen to reflect items that will be completed prior to implementation of Phase II. The CD or DVD should include all pages of the final product. A copy of draft versions of these deliverables are not required on CD or DVD.

3. ***What is the purpose of the public web site? It appears that the information to be provided on the public web site should be available through www.clinicaltrials.gov. If content on the web site is to be used for subject recruitment, does the content need to be approved by the IRBs at each RCC before it can be posted*****?*** ***If so, we anticipate substantial difficulties in updating the website in a timely manner.***

   As noted in C.1. the public web site will provide information about the trial to prospective research subjects and the lay public. This information shall include a summary of study aims, design, schedule, and eligibility criteria; a listing of the RCCs with contact information; and a link to the NHLBI public web site. As you indicate there may be other options available for notifying the public of this study. These options can be addressed in your technical proposal as part of your technical approach.

   A trial must be approved by an IRB prior to posting at www.clinicaltrials.gov. While there is no requirement to have IRB approval at each participating site prior to completing the content for the web page, a contract site that has not obtained IRB approval will not be allowed to recruit subjects.

4. ***Does NHLBI plan to have centralized reading of spirometry or other tests to provide some quality control of assessments conducted at the RCCs? If so, should resources for these central reading sites be included in the DCC proposed budget?***

   There is no requirement in the solicitation to have a central reading site for spirometry or other LOTT procedures. If you believe that a central site is the best approach to achieve quality control you would want to address this as part of your technical approach.

5. ***On page 6, part 12d, the RFP states that the Medical Monitor shall attend all DSMB meetings and on page 56, part 12, the 1st paragraph states that the PI and two "additional staff will attend the DSMB meetings. For budgeting purposes, is the Medical Monitor considered one of the two additional staff, or should the DCC budget include travel for a total of 4 individuals to DSMB meetings?***

For cost proposal purposes you should plan on having the PI, Medical Monitor and 2 additional staff shall attend biannual meetings of the DSMB, which will last 1 day and be held in Bethesda, MD. If during discussions it decided that the number of attendees should be less than four you will be asked to remove the excess travel costs.

6. ***Is the DCC responsible for designing and implementing data management systems for substudies funded through other sources and for analyses of data from those studies? If so, does NHLBI have a sense of the number and size of such studies that should be used for DCC budgeting purposes?***

   As indicated on page 7 of the solicitation, "d. The DCC shall work with the SC in the writing of Manual of Operations chapters that detail the methods, procedures, and operations of **substudies** approved for implementation by the NHLBI." The DCC will not be responsible for designing, implementing or data management of **ancillary** studies.

   Substudies are considered part of the overall program, whereas ancillary studies fall outside of the program. Typically, an ancillary study will be proposed by an investigator that wants access to LOTT samples or data and has funding from another source. In this case the Steering Committee would either approve or deny access to the LOTT samples or data. Whereas a substudy, is part of the LOTT and funding is included in the contract price. The DCC will be responsible for the design and data management associated with the LOTT substudies.

7. ***For budgeting purposes, should we assume that all subcommittee face-to-face meetings are held in conjunction with Steering Committee meetings?***

   For proposal preparation purposes you should assume that the Subcommittee will meet in conjunction with the Steering Committee and as needed by conference calls.