AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID NO.	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(if applicable)*
001	June 4, 2004		

6. ISSUED BY — CODE

National Institutes of Health
National Heart, Lung, and Blood Institute
Rockledge II, Room 6224
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-HV-05-08
Interagency Registry of Mechanical Circulatory Support for
End-Stage Heart Failure

CODE | FACILITY CODE

(✓)	9A. AMENDMENT OF SOLICITATION NO.
	RFP NHLBI-HV-05-08
✓	9B. DATED *(SEE ITEM 13)*
	May 19, 2004
	10A. MODIFICATION OF CONTRACT/ORDER NO.
	10B. DATED *(SEE ITEM 13)*

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.)*

Recently received inquiries and responses are discussed on page two. In addition, amendments to specific sections of the RFP are indicated 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)*	
		Douglas W. Frye Contracting Officer, Contracts Operations 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)*	6/4/04

1. **Question**: Background/Statement of Work, page 3, item 3 references proprietary (device specific) information for device prototypes. Does this imply that this Registry may include data collected under IDE, possibly to be included in a PMA submission?

   Response: It is the intent of the registry to collect and analyze device, and patient outcomes in order to facilitate knowledge of the performance of devices and management of patients and to expedite device development and improve patient management. While it is not likely that IDE information will be required, offerors should have the capacity to handle information in a way that can transfer data to the federal agency such that proprietary information is kept confidential.

2. **Question**: Background/Statement of Work, page 4, item 8 (ii) references serious adverse events (SAEs) to be reported in 48 hours. Should this reference unanticipated adverse device effects (UADEs) instead?

   Response: It's expected that the Registry will establish procedures to define and collect adverse events that will meet or exceed FDA reporting requirements. In order to avoid the need for duplicate reporting to the Registry and to the FDA, offerors should consider how registry collected data on adverse events can be transmitted when appropriate to the FDA to meet post market reporting requirements.

3. **Question**: Statement of Work, page 4, item 16. How far back should retrospective data be collected? January 1, 2004? October 1, 2003?

   Response: The value and need for retrospective data, and the time window for its collection should be decided by the steering committee. Offerors should include the capability to collect retrospective data and discuss its value relative to prospective collection given the objectives of the registry.

4. **Question**: Is the repository subsumed under a current NIH contract or will this work be separately competed?

   Response: NHLBI supports, through a separate contract, a tissue repository capable of storing tissue and blood specimens collected in the Registry. Offerors are requested to establish procedures for collection and shipping to the NHLBI-supported facility and to establish procedures to access specimens for study investigators as well as researchers outside the study.

5. **Question**: Who proposes/appoints the Study Chair?

   Response: NHLBI will appoint the Study Chair.

6. **Question**: Is there a plan and/or additional funds to reimburse sites for their effort?

   Response: No, participation in the registry will satisfy CMS requirement for reimbursement that patient be entered into an independent registry. Participation in the Registry should facilitate CMS reimbursement and will be an important incentive for maintaining compliance with registry procedures.

7. LIST OF ATTACHMENTS, SECTION J, Informational Attachments is amended to include the Privacy Act System of Records Number, 09-25-0200. System of Records No. 09-25-0200 can be viewed at: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

8. PACKAGING AND DELIVERY OF THE PROPOSAL, External Package Marking, the number of Technical Proposal copies to be shipped is amended to read:

   TECHNICAL PROPOSAL: ORIGINAL* AND TWENTY-FIVE (25) COPIES

9. SECTION L, Instructions, Conditions and Notices to Offerors–Specific to this RFP, Part II General Instructions, item 49 is amended to delete the following two FAR clauses:

   Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
   Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

10. The Table of Contents for this RFP incorrectly included "Central Laboratory" in the title at time of posting. The correct title for the RFP is: Interagency Registry of Mechanical Circulatory Support for End-Stage Heart Failure.