

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>	1. CONTRACT ID NO.	PAGE OF PAGES 1   2
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2. AMENDMENT/MODIFICATION NO. <p style="text-align: center;">003</p>	3. EFFECTIVE DATE <p style="text-align: center;">July 23, 2004</p>	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)
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6. ISSUED BY  National Institutes of Health National Heart, Lung, and Blood Institute Rockledge II, Room 6224 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902	CODE	7. ADMINISTERED BY (if other than Item 6)  CODE
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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	(✓)	9A. AMENDMENT OF SOLICITATION NO. <p style="text-align: center;">RFP NHLBI-HV-05-08</p>
	✓	9B. DATED (SEE ITEM 13) <p style="text-align: center;">May 19, 2004</p>
		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 the following continuation 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) <p style="text-align: center;">Douglas W. Frye Contracting Officer, Contracts Operations Branch</p>
15B. CONTRACTOR/OFFEROR  <p style="text-align: center;">_____ (Signature of person authorized to sign.)</p>	15C. DATE SIGNED
16B. UNITED STATES OF AMERICA BY <p style="text-align: center;">/s/ _____ (Signature of Contracting Officer)</p>	16C. DATE SIGNED <p style="text-align: center;">7/23/04</p>

1. **Question:** Although a physician is mentioned on page 6 of the project description, I did not see requirements for specialty, experience level, etc. Does this person have to be a cardiologist? Also, 40% FTE is a lot; what activities do you see the physician performing? Can I name this person later, or is it required in the proposal?

**Response:** The physician, who may or may not serve as the Principal Investigator or Co-Investigator, needs to have the appropriate expertise and experience to advise the registry on clinical matters. Offerors are advised to name the physician in their proposals and provide a curriculum vitae or biosketch to ensure that the reviewers have ample information to evaluate the proposal. Please also refer to question and answer No. 2 in Amendment No. 002 to the RFP and technical evaluation criteria Nos. 2.a and 2.b of Section M “Evaluation Factors for Award.”

2. **Question:** What is the function of the program assistant?

**Response:** While a Program Assistant is listed in the RFP as a labor category, it is not a mandatory position. The work performed by this position might include, but not be limited to, communication with clinical sites, site visits for assessment of data quality, and training of staff at clinical sites.

3. **Question:** I assume dictionary coding (i.e. MedDRA, WHO Drug) of medications and adverse events is required to meet FDA expectations?

**Response:** There is no additional information that can be provided in response to this question. Please refer to question and answer No. 9 in Amendment No. 002 to the RFP.