

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE _____ PAGE OF PAGES
 1 | 3

2. AMENDMENT/MODIFICATION NO. **004** 3. EFFECTIVE DATE **03/20/2003** 4. REQUISITION/PURCHASE REQ. NO. _____ 5. PROJECT NO. (If applicable) _____

6. ISSUED BY CODE _____ 7. ADMINISTERED BY (If other than Item 6) CODE _____
 National Heart, Lung, & Blood Institute, NIH
 Rockledge II Building, Room 6110
 6701 ROCKLEDGE DR MSC 7902
 BETHESDA MD 20892-7902

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
 Recipients of BAA NHLBI-HV-04-01,
 Pediatric Circulatory Support

9A. AMENDMENT OF SOLICITATION NO. **BAA NHLBI-HV-04-01**
 9B. DATED (SEE ITEM 13) **November 29, 2002**
 10A. MODIFICATION OF CONTRACT/ORDER NO. _____
 10B. DATED (SEE ITEM 13) _____

CODE _____ FACILITY CODE _____

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 _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offers 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 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.)

Recently received inquiries are discussed on the following pages concerning subcontract, intellectual property, and other matters.

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) Robert A. Julia Contracting Officer, HLVD Contracts Section	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign.)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY _____ /s/ _____ (Signature of Contracting Officer)	16C. DATE SIGNED 03/20/2003

The following inquiry has been received: “Can one of our subcontractors be a foreign entity? Can I purchase components that are manufactured outside the US?”

The following response applies:

Foreign subcontracts will not be accepted. Purchase of foreign components is acceptable; however, if there are rights or ownership issues that convey with the components, then these issues need to be identified and discussed in the proposal.

This amendment does not alter the source selection criteria or procedures of the solicitation as posted and subsequently amended.

The following inquiry has been received: “I am considering a submission in response to the pediatric support RFP that would require partnering with a corporate organization. Before proceeding, the question has been raised by this corporate organization about any obligation, royalties, and intellectual property management they would owe the NIH if the proposal were funded.”

The following response applies:

Each resulting contract will contain intellectual property clauses appropriate to the proposal as negotiated. Existing intellectual property that a contractor or subcontractor might bring to the program would be retained by that organization. The intellectual property that arises from the program would be retained in accordance with the terms of the contract. Typically, the contractor is allowed to retain the intellectual property rights in accordance with the clauses arising from the Bayh-Dole Act. Those same clauses give the Government unlimited rights to “use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.”

Also, the typical clause we use states that the “Contractor has the responsibility to obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor’s obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government such rights, the Contractor shall promptly bring such refusal to the attention of the Contracting Officer and not proceed with subcontract award without further authorization.” We would review the subcontract before approval to make sure that this occurs, and if we believe it is warranted, we would have an acceptable subcontract in hand before we award the prime contract.

Additional guidance concerning intellectual rights issues is described at <http://ott.od.nih.gov/NewPages/64FR72090.pdf> as indicated near the bottom of page 18 of the BAA.

This explanation is provided as guidance to potential offerors and does not supersede any terms of the solicitation.

The following inquiry has been received: “In Task 1 there is reference to ‘physiologic performance for the normal and diseased heart conditions.’ We are interpreting this statement to mean our device’s physiologic performance and NOT the physiologic performance of the patient’s native heart. Is this correct?”

The following response applies:

The question is believed to refer to task 1 of the sample statement of work (SOW) on page 4 of the solicitation or BAA. Offerors must read the last three italicized sentences preceding task 1 in the sample statement of work on page 4 and be sure also to read Part I of Section L on pages 30-34 before drafting a proposed statement of work.

This explanation is provided as guidance to potential offerors and does not supersede any terms of the solicitation.

The following inquiry has been received: “Directions for the ‘Past Performance Information’ section only request information about contracts. Should we interpret this to mean only the contract form of funding or the more general Federal contracts and grants?”

The following response applies:

For the purpose of item 3 of the Business Proposal Instructions, as set forth from the bottom of page 46 to the top of page 47, the text of the solicitation means what it says. Offerors must provide references for contracts, for which past performance is required to be rated. Grants are not included in this past performance section.

This explanation is provided as guidance to potential offerors and does not supersede any terms of the solicitation.