SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 48

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	BAA NHLBI-HV-04-01	☐ SEALED BID (IFB) ☑ NEGOTIATED (RFP)	11/29/2002	

7. ISSUED BY	CODE	8. ADDRESS OFFER TO *(If other than Item 7)*
National Heart, Lung, & Blood Institute, NIH Rockledge 2, Room 6110 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902		Review Branch, Division of Extramural Affairs National Heart, Lung, and Blood Institute, NIH Rockledge 2, Room 7091 6701 ROCKLEDGE DR MSC 7924 BETHESDA MD 20892-7924

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder"

SOLICITATION

9. Sealed offers in original and 25* copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if hand carried, in the depository located in [Block 8] *But see p. 36 4:30 pm (Hour) local time 05/21/2003 (Date)

INTENT NOTICE DUE 03/21/2003; SEE P. 35

CAUTION – LATE Submissions, Modifications, and Withdrawals: See Section L. Provision No. 52.214-7 or 52.215-10. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)*			C. E-MAIL ADDRESS
		AREA CODE	NUMBER	EXT.	
	Robert A. Julia	301	435-0340	NA	rj12s@nih.gov

(✓)	SEC.	PART I -- THE SCHEDULE		(✓)	SEC.	PART II -- CONTRACT CLAUSES	
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OFFER *(Must be fully completed by offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 270 calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52.232-8*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS %

14. ACKNOWLEDGMENT OF AMENDMENTS *(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated:)*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER *(Type or print)*

15B. TELEPHONE NO. AREA CODE/NUMBER	EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE -- ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c) ( ) ☐ 41 U.S.C. 253(c) ( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM

24. ADMINISTERED BY *(If other than Item 7)* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE

IMPORTANT -- Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

PEDIATRIC CIRCULATORY SUPPORT
BAA NHLBI-HV-04-01

[This Solicitation, Offer, and Award is a Broad Agency Announcement, a special type of Request for Proposals or RFP. The text below in Sections B through K represents the anticipated language of a contract that would result from an award pursuant to this solicitation with information and editing as required appropriate to the successful proposal and offeror as awarded. Offerors may edit or substitute the clauses below as needed to represent their organization type and proposed contract type. Solicitation provisions and contract clauses are included below as required for negotiated acquisitions pursuant to a Request for Proposals.

[Sample contract clauses follow below. For further guidance to fill out your proposal and/or to obtain variant clauses appropriate to your offer, see http://ocm.od.nih.gov/contracts/rfps/SAMPKT.HTM#B. This draft is based on an anticipated Cost type, completion form, incrementally funded research contract. Proposals for other contract types and forms should be altered accordingly to use the appropriate clauses and language. RFP provisions and instructions may be found at: http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm.]

SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This Broad Agency Announcement (BAA) will establish multidisciplinary research teams. Each team will perform basic and applied research to develop novel circulatory assist devices or other bio-engineered systems for infants and children with congenital and acquired cardiovascular disease who experience cardiopulmonary failure and circulatory collapse. The BAA is intended to complement and enhance ongoing NHLBI research programs in pediatric cardiovascular disease. The BAA also complements the Institute's circulatory support/artificial heart program.

ARTICLE B.2. ESTIMATED COST

a. The estimated cost of this contract is $

b. Total funds currently available for payment and allotted to this contract are $. For further provisions on funding see the LIMITATION OF FUNDS clause referenced in Article I.2., Authorized Substitutions of Clauses.

c. It is estimated that the amount currently allotted will cover performance of the contract through February 14, 2005.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the contractor.

e. Future increments to be allotted to this contract are estimated as follows:

Period	Amount
02/15/2004 - 02/14/2005	
02/15/2005 - 02/14/2006	
02/15/2006 - 02/14/2007	
02/15/2007 - 02/14/2008	
02/15/2008 - 02/14/2009	
Total	

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

(1) Acquisition, by purchase or lease, of any interest in real property;

(2) Special rearrangement or alteration of facilities;

(3) Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

(4) Travel to attend general scientific meetings;

(5) Patient care costs;

(6) Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the *Contractor's Guide for Control of Government Property*, 1990), regardless of acquisition value.

b. Travel Costs

Domestic Travel

(1) Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $_____ without the prior written approval of the Contracting Officer.

(2) The Contractor shall invoice and be reimbursed for all travel costs in accordance with OMB Circular A-21.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. *[Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurring the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article as agreed upon by both parties during negotiations.]*

SECTION C—DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, Section J, Attachment 1, attached hereto and made a part of this contract.

[Contracts awarded as a result of this BAA will incorporate the Statement of Work proposed by the offeror and negotiated and accepted by the Government and shall be incorporated in Section J,

Attachment 1 or referenced herein and considered a part of the Statement of Work. A sample Statement of Work follows below and may be replaced by the offeror's Statement of Work.]

[Refer to Section L, Subsection I for essential technical information and Section M for evaluation factors.]

[This solicitation is not intended primarily to fund formal device readiness and reliability testing. In order to achieve the goals of this BAA, a statement of work organized into sequential tasks is recommended. The proposal must address the work, proposed costs, program plan on a task-by-task basis, organizational structure with appropriate time schedules, and specific descriptions of work elements and methodology. Because this announcement is soliciting research for a family of devices and an offeror may be proposing research for only one of the device systems described below, the offeror must submit a statement of work specific to the research proposed. Typical work elements are described here for illustrative purposes. Typical work elements or tasks should, as an example, include the following.]

Task 1. Design and Analysis

The contractor shall perform appropriate theoretical studies to justify the concepts described in the proposal. These studies may include mathematical modeling and/or computer simulations of the proposed concept, corrosion controls, physiologic performance for the normal and diseased heart conditions, reliability model for the proposed device, and failure mode analyses.

Task 2. Research and Development Components

The contractor shall perform research to implement concepts for a new and/or improved circulatory support system, such as an energy converter, blood pump, control system, and power source as well as for improved biocompatibility. The outcome of this research will be the development of new or improved implantable and extracorporeal components.

Task 3. Research and Development of the Proposed System

The contractor shall perform research involving the complete system that considers factors such as input power requirements; stage-by-stage efficiency; gyroscopic effects, size, weight, and specific gravity and density of the device; placement of the device; biocompatibility; repair and maintenance; and sensitivity to the environment. Control systems should be simple, self-regulatory, and programmable.

Task 4. Fabrication and Manufacturability

The contractor shall fabricate systems that will be tested *in vitro* and/or *in vivo*. Effort shall be extended to develop fabrication procedures, documentation, materials control, and acceptance procedures. Manufacturability of components and a complete system must be addressed in the system design. Design should take into consideration the risk of obsolescence should purchased parts become unavailable.

Task 5. *In Vitro* Testing and Evaluation

The contractor shall perform *in vitro* tests, as necessary, to demonstrate the transient and chronic performance characteristics of the completed system.

Task 6. *In Vivo* Evaluation

Evaluation of the complete proposed system in animals shall be accomplished by the contractor. The evaluation shall include the recording of appropriate physiologic and hematol-

ogic parameters of animals with implants and the recording of the performance of the implanted system. Necropsy studies and evaluation of the state of the system before, during, and after implant shall be part of this evaluation.

Task 7. Biocompatibility

The biocompatibility of candidate materials shall be evaluated by both component testing and whole system testing, as necessary, *in vitro* and *in vivo*. This evaluation shall address the interactions between the materials and both blood and tissues with which a system will come in contact. Compatibility should take into account thermal regulation and hermetic sealing. Data shall be collected before and at several time points during operation, as well as following the implant period, and measures of biocompatibility as a function of time shall be documented.

Task 8. Quality Control Programs

In the later phase of the proposed program, the contractor shall implement quality control procedures over all phases of purchase, inspection, fabrication, assembly, and testing of components and the entire system in accordance with Food and Drug Administration Good Manufacturing Practices (GMP) and International Organization for Standardization (ISO) 9000 documents, as appropriate. Configuration control, deficiency reporting system, and related effort must be included in this task.

Task 9. Reliability

The contractor shall analyze the results of theoretical, experimental studies, and *in vitro* use to estimate future reliability and performance of the system in relation to the proposed clinical use.

Task 10. Publications

The contractor shall prepare scientific and technical papers of research and development performed under this contract for publication in scientific journals. Some publications, one to two per year, may be considered as collaborative efforts among the several contractors supported in this program.

b. In carrying out the Statement of Work, the contractor shall ensure that quality assurance and quality control standards are established, documented, and followed to assure both accuracy and precision of the resources and data generated by the program.

c. Technology and scientific advances are expected to occur during the contract performance period. In order to keep pace with state-of-the-art advances, changes may be required to the Technical Plan. A scientific Progress Review Panel will be established by the NHLBI to monitor progress, review study findings/data and safety, and make recommendations to the NHLBI.

d. The Program Plan, referenced in Article C.2., paragraph a., shall be used to monitor contractor performance. Upon receipt, the Program Plan and any amendments thereto are incorporated by reference.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

[In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract

resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined during negotiations.

[For proposal preparation purposes only, it is estimated that copies of these reports will be required as described below. These reports are intended for use by all contractors in the program. For reports containing confidential or proprietary data, edited reports shall be submitted to the collaborating contractors and full reports, appropriately marked as to confidential data, shall be submitted to the Contracting Officer and the Project Officer.]

In addition to those reports required by the other terms of this contract, the contractor shall prepare and submit the following reports in the manner stated and in accordance with Article F.1. DELIVERIES of this contract:

1. Program Plan: A program plan that provides a detailed description of the activities for the entire contractual period, presented in a time-oriented sequence. This program plan must be submitted not later than 30 days after contract award and annually thereafter. For clarity and brevity, one-page charts shall be utilized whenever possible. The program plan must receive NHLBI approval prior to the start of the research.

2. Quarterly Progress Reports: A progress report that describes the work performed during the prior three-month period. These reports are not required for calendar quarters when the following reports are due.

3. Draft Annual Reports: Comprehensive annual reports that shall serve as technical reference documents. These documents shall describe the objectives of the work, all of the activities with significant scientific data, the results of the previous nine months' efforts (including publications) and a perspective of these results related to published data. The draft annual reports are due three months before the contract anniversary date as part of the annual incremental funding package. The draft shall cover a period of nine months. This report is not required when the Draft Final Report is due.

4. Annual Reports: Comprehensive annual reports that shall serve as technical reference documents. These documents shall describe the objectives of the work, all of the activities with significant scientific data, the results of the year's efforts (including publications), and a perspective of these results relative to published data. Each annual report shall include the draft annual report and any additional data over the twelve-month period. This report is not required when the Final Report is due.

5. Draft Final Report: In the fifth year, a draft final report is due three months before the contract completion date. This report shall be similar in content to the annual reports plus a summary of significant activities from all prior years.

6. Final Report: In the fifth year, the final report is due on the completion date of the contract, comprising all content, corrections, and updates to the draft final report.

7. Technical Data Package: At the end of the contract period, the contractor shall deliver to the NHLBI a technical data package, including a complete set of engineering drawings and one complete pediatric circulatory support system developed during their program.

8. Financial Reports: Contractors paid under the DHHS Payment Management System shall submit monthly Contract Financial Reports (three copies) using form NIH 2706. (This report will be listed in a separate article and is omitted from the list in Article F.1. below.)

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted within 90 days after contract expiration to the following address:

Contracting Officer
National Institutes of Health
National Heart, Lung, and Blood Institute
Rockledge 2, Room 6110
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D—PACKAGING, MARKING, AND SHIPPING

The Contractor shall guarantee that all required materials shall be delivered in immediately usable and acceptable condition.

SECTION E—INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this article the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

National Institutes of Health
National Heart, Lung, and Blood Institute
Rockledge 2, Room 6110
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT—(SHORT FORM) (APRIL 1984).

SECTION F—DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of this contract shall be deemed to occur upon performance of the statement of work as set forth in Article C.1. and delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

The items specified below as described in Section C, Article C.2. shall be delivered f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES (APRIL 84) and in accordance with and by the date(s) specified below [and any specifications stated in Section D, PACKAGING,MARKING AND SHIPPING, of this contract]:

Item	Description	Delivered to:	Delivery Schedule
1.	Program Plan	Project Officer and Contracting Officer	Within thirty days following contract award and annually thereafter.
2.	Quarterly Progress Reports	Project Officer, Contracting Officer, and collaborating contractors	On the fifteenth calendar day following completion of each three months of performance, except when one of the following reports is due.
3.	Draft Annual Reports	Project Officer and Contracting Officer	3 months before the contract anniversary date except when item 5. below is required.
4.	Annual Reports	Project Officer, Contracting Officer, and collaborating contractors	On the final day of each year of contract performance except when item 6. below is required.
5.	Draft Final Report	Project Officer and Contracting Officer	3 months before the contract completion date.
6.	Final Report	Project Officer, Contracting Officer, and collaborating contractors	On the completion date of the contract.
7.	Technical Data Package	Contracting Officer	On the completion date of the contract.

[It may be necessary to revise this delivery schedule based on information included in the proposals received in response to the BAA.] Deliverables shall be sent to the following addresses:

Addressee	Item	Quantity
Project Officer Clinical and Molecular Medicine Program, DHVD, NHLBI 6701 ROCKLEDGE DR MSC 7940 BETHESDA MD 20892-7940	1-6	5 each
Contracting Officer Contracts Operations Branch, DEA, NHLBI 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902	1-7	1 each
The collaborating contractors (List to be developed)	2, 4, 6	1 each per contractor

ARTICLE F.2. STOP WORK ORDER

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.242-15, STOP WORK ORDER (AUGUST 1989) with ALTERNATE I (APRIL 1984).

SECTION G—CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer will represent the Government for the purpose of this contract:

[To be named]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer hereby designates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individuals are considered to be essential to the work being performed hereunder:

NAME	TITLE
[To be named]	Program Manager
[(and others as deemed appropriate)]	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

An original and two copies to the following designated billing office:

Robert A. Julia
Contracting Officer
Contracts Operations Branch
National Heart, Lung, and Blood Institute, NIH
Rockledge 2, Room 6110
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 435-0340.

ARTICLE G.3. LETTER OF CREDIT PAYMENT INFORMATION *[Alternate]*

Advance payments will be provided under Letter of Credit Number **7508**____ in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html).

(1) Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

An original and two copies to the following office:

Robert A. Julia
Contracting Officer
Contracts Operations Branch
National Heart, Lung, and Blood Institute, NIH
Rockledge 2, Room 6110
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

(2) Inquiries regarding payments should be directed to the following office administering advance payments:

Division of Payment Management
11400 Rockville Pike
ROCKWALL BLDG #1 SUITE 700
ROCKVILLE MD 20852
http://www.dpm.psc.gov/support/contact

ARTICLE G.4. CONTRACT FINANCIAL REPORT *[To be used only with Alternate G.3]*

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "PREPARATION INSTRUCTIONS," all columns A through J shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full calendar month following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a monthly basis.

d. The Contracting Officer may require the contractor to submit detailed support for costs contained in one or more interim financial reports. This article does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is identified in Financial Report of Individual Project/Contract, NIH 2706, attached hereto and made a part of this contract as Attachment 3, in Section J.

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, Section I, the cognizant Contracting Officer responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Chief, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 EXECUTIVE BLVD RM 6B05 MSC7540
BETHESDA MD 20892-7540

[Additional guidance on indirect costs is available from the Division of Financial Advisory Services, Office of Acquisition Management and Policy at http://ocm.od.nih.gov/dfas/idcsubmission.htm.]

ARTICLE G.5. GOVERNMENT PROPERTY

In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in Section I of this contract, the Contractor shall comply with the provisions of DHHS Publication, *Contractor's Guide for Control of Government Property* (1990), which is incorporated into this contract by reference. Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contract Property Administrator.

Requests for information regarding property under this contract should be directed to the following office:

Contracts Property Administrator
Division of Personal Property Services, NIH
6011 Building, Suite 637
6011 EXECUTIVE BLVD MSC 7670
BETHESDA MD 20892-7670 Telephone: (301) 496-6466

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, one interim evaluation will be performed.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address: http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H—SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they

consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. HUMAN SUBJECTS *[Alternate]*

The Contractor shall provide to the Contracting Officer on an annual basis a properly completed Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration certifying IRB review and approval of the protocol(s). The human subject certification can also be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310. Section K, incorporates the protocols approved under this contract.

ARTICLE H.3. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS *[Alternate]*

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts, announcement dated June 5, 2000 located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. HUMAN MATERIALS *[Alternate]*

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence his/her donation of human material.

The contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved assurances, whether domestic or foreign, and compliance must be ensured by the contractor.

Provision by the contractor to the Contracting Officer of a properly completed Optional Form 310 certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the Optional Form 310.

ARTICLE H.3. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violations of the Act may involve the imposition of criminal penalties. This document is incorporated into this contract as Attachment 3.

The Privacy Act System of Records applicable to this project is Number 09-25-0200, Clinical, Epidemiology and Biometric Studies of the NIH. The notice was published in the Federal Register, Volume 64, number 229 on November 30, 1999 (http://www.access.gpo.gov/su_docs/aces/PrivacyAct.shtml).

ARTICLE H.3. ANIMAL WELFARE ASSURANCE *[Alternate]*

Under governing policy, federal funds administered by the Public Health Service (PHS) shall not be expended for research involving live vertebrate animals without prior approval by the Office for Laboratory Animal Welfare (OLAW), of an assurance to comply with the PHS policy on humane care and use of laboratory animals. This restriction applies to all performance sites without OLAW-approved assurances, whether domestic or foreign.

The contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

ARTICLE H.4. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis,

cloning, or any other means from one or more human gametes or human diploid cells.. If this is a multi-year contract, it may be subject to unilateral modifications by the Government to incorporate future DHHS appropriation acts.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b.

Public Law	Fiscal Year	Period
P.L. 107-116, §510	2002	10/01/2001 - 09/30/2002

ARTICLE H.5. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. If this is a multi-year contract, it may be subject to unilateral modifications by the Government to incorporate future DHHS appropriation acts.

b.

Public Law	Fiscal Year	Period
P.L. 107-116, §505	2002	10/01/2001 - 09/30/2002

ARTICLE H.6. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multi-year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

b.

Public Law	Fiscal Year	Dollar Amount of Salary Limitation
P.L. 107-116	2002	Executive Level I

c. Effective January 1, 2002 for contract expenditures using FY2002 funds, the Executive Level I rate is $166,700 and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the following web site for Executive Schedule rates of pay: FY2002 EXECUTIVE LEVEL SALARIES: http://www.opm.gov/oca/02tables/ex.htm.

ARTICLE H.7. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

a. The Contractor agrees to comply with the Information Technology system security and/or privacy specifications set forth in the Statement of Work, the Computer Security Act of 1987, Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May 1994). The Contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract.

b. OMB A-130 is accessible via web site: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt. The DHHS Automated Information Systems Security Program Handbook is accessible via web site: http://wwwoirm.nih.gov/policy/aissp.html

ARTICLE H.8. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/news/508-final.htm.

ARTICLE H.9. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are deliverables under the procurement or are purchased by the contractor using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

ARTICLE H.10. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

> This project has been funded in whole or in part with Federal funds from the National Heart, Lung, and Blood Institute, National Institutes of Health, under Contract No. N01-HV-4_____.

ARTICLE H.11. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources. If this is a multi-year contract, it may be subject to unilateral modifications by the Government to incorporate future DHHS appropriation acts.

b.

Public Law	**Fiscal Year**	**Period**
P.L. 107-116, §507	2002	10/01/2001 - 09/30/2002

ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in

writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
PO BOX 23489
WASHINGTON DC 20026-3489

ARTICLE H.13. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

YEAR 2000 COMPLIANCE—SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY: The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

ARTICLE H.14. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself. If this is a multi-year contract, it may be subject to unilateral modifications by the Government to incorporate future DHHS appropriation acts.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. If this is a multi-year contract, it may be subject to unilateral modifications by the Government to incorporate future DHHS appropriation acts.

c.

Public Law and Section no.:	**Fiscal Year**	**Period**
for a., above: P.L. 107-116, §503(a)	2002	10/01/2001 - 09/30/2002
for b., above: P.L. 107-116, §503(b)	2002	10/01/2001 - 09/30/2002

ARTICLE H.15. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, Section J, Attachment 5, is attached hereto and made a part of this contract.

(2) The failure of any contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

(1) The contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

The Report shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Heart, Lung, and Blood Institute
Rockledge 2, Room 6110
6701 ROCKLEDGE DRIVE MSC 7902
BETHESDA MARYLAND 20892-7902

(2) The contractor shall submit one (1) copy of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract: October 30th

The first Report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. One copy of this report shall be sent to the Contracting Officer at the address above. One copy of this Report shall be mailed to the Office of Small and Disadvantaged Business Utilization, DHHS at the following addresses:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 517-D
200 INDEPENDENCE AVE SW
WASHINGTON DC 20201-0004

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The contractor should call SBA Headquarters in Washington, DC at (202) 606-4000, X234 for the correct address if unknown.

ARTICLE H.16. OBTAINING/DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts" (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://ott.od.nih.gov/NewPages/64FR72090.pdf, is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

***Note**: For the purposes of this Article, the terms "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.*

ARTICLE H.17. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at http://www.usfa.fema.gov/hotel/index.htm.

PART II—CONTRACT CLAUSES

SECTION I—CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS—FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available [FAR 52.252-2 (JUNE 1988)]. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records—Negotiation (Over $100,000), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence—Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data

FAR CLAUSE NO.	DATE	TITLE
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data—Modifications
52.216-7	Feb 2002	Allowable Cost and Payment (Paragraph (a) is modified to delete the words “Subpart 31.2” and to add the words “Subpart 31.3”)
52.216-11	Apr 1984	Cost Contract—No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages—Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Affirmative Action for Special Disabled Veterans, Veterans of the Vietnam Era, and and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act—Balance of Payments Program—Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights—Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost

FAR CLAUSE NO.	DATE	TITLE
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer—Other Than Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in Article B.4., Advance Understandings
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions—with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance—Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES:

[Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations. It is expected that the following clause(s) will be made part of the resultant contract:]

ARTICLE I.1. of this Section is hereby modified as follows:

FAR Clause 52.232-20, LIMITATION OF COST (APRIL 1984), is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984), is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

[Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:]

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR 52.216-15, Predetermined Indirect Cost Rates (APRIL 1998).
2. FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

   "(c) Waiver of evaluation preference.....

   [ ] Offeror elects to waive the evaluation preference."
3. FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (MAY 2001), ALTERNATE I (OCTOBER 1998).
4. FAR 52.223-5, Pollution Prevention and Right-to-Know Information (APRIL 1998).
5. FAR 52.224-1, Privacy Act Notification (APRIL 1984).
6. FAR 52.224-2, Privacy Act (APRIL 1984).
7. FAR 52.227-14, Rights in Data—General (JUNE 1987), Alternate IV (JUNE 1987).
8. FAR 52.227-17, Rights in Data—Special Works (JUNE 1987).
9. FAR 52.230-5, Cost Accounting Standards—Educational Institution (APRIL 1998).
10. FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).
11. FAR 52.242-3, Penalties for Unallowable Costs (OCTOBER 1995).
12. FAR 52.243-2, Changes—Cost Reimbursement (AUGUST 1987), Alternate V (APRIL 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS/ PUBLIC HEALTH SERVICE ACQUISITION REGULATIONS (HHSAR) (PHSAR) (48 CFR CHAPTER 3) CLAUSES:

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

1. HHSAR 352.270-1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (JANUARY 2001).
2. HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

3. HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clause(s) are attached and made a part of this contract:

1. NIH(RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

2. NIH(RC)-11, Research Patient Care Costs (4/1/84).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

[Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:]

a. ALTERNATE V, ADVANCE PAYMENT WITHOUT SPECIAL ACCOUNT (MAY 2001), ALTERNATE II (MAY 2001), and ALTERNATE IV (APRIL 1984), of FAR Clause 52.232-12, ADVANCE PAYMENTS (MAY 2001).

(a) Requirements for payment. Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the contractor, and approval by the administering office, NA, or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed $ NA . If a letter of credit is used, the contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The contractor shall apply terms similar to this clause to any advance payments to subcontractors.

(b) Use of funds. The contractor may use advance payment funds only to pay for properly allocable, allowable, and reasonable costs for direct materials, direct labor, and indirect costs. Determinations of whether costs are properly allocable, allowable, and reasonable shall be in accordance with generally accepted accounting principles, subject to any applicable subparts of Part 31 of the Federal Acquisition Regulation.

(c) Repayment to the Government. At any time, the contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the contractor's current requirements or the amount specified in paragraph (a) of this clause.

(d) Maximum payment. When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost amount (not including fixed-fee, if any) for the work under this contract, the Government shall withhold further payments to the contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the contractor all unliquidated advance payments and interest charges payable. The contractor shall pay any deficiency to the

Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed the total estimated contract amount. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.

(e) Interest. No interest shall be charged to the prime contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime contractor.

(1) The contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate in subparagraph (e)(3) of this clause. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge--

(i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check;

(ii) Repayments by contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer; and

(iii) Liquidations by deductions from Government payments to the contractor shall be considered as decreasing the unliquidated balance as of the date of the check for the reduced payment.

(2) Interest charges resulting from the monthly computation shall be deducted from payments, other than advance payments, due the contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon satisfactory completion or termination of the contract for the convenience of the Government. The contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors, for experimental, developmental, or research work.

(3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.

(4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the contractor shall pay the remaining interest to the Government on demand.

(f) Lien on property under contract. (1) All advance payments under this contract, together with interest charges, shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, on the supplies or other things covered by this contract and

on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the contractor.

(2) The contractor shall identify, by marking or segregation, all property that is subject to a lien in favor of the Government by virtue of any terms of this contract in such a way as to indicate that it is subject to a lien and that it has been acquired for or allocated to performing this contract. If, for any reason, the supplies, materials, or other property are not identified by marking or segregation, the Government shall be considered to have a lien to the extent of the Government's interest under this contract on any mass of property with which the supplies, materials, or other property are commingled. The contractor shall maintain adequate accounting control over the property on its books and records.

(3) If, at any time during the progress of the work on the contract, it becomes necessary to deliver to a third person any items or materials on which the Government has a lien, the contractor shall notify the third person of the lien and shall obtain from the third person a receipt in duplicate acknowledging the existence of the lien. The contractor shall provide a copy of each receipt to the Contracting Officer.

(4) If, under the termination clause, the Contracting Officer authorizes the contractor to sell or retain termination inventory, the approval shall constitute a release of the Government's lien to the extent that--

(i) The termination inventory is sold or retained; and

(ii) The sale proceeds or retention credits are applied to reduce any outstanding advance payments.

(g) Insurance. (1) The contractor shall maintain with responsible insurance carriers—

(i) Insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality;

(ii) Adequate insurance against liability on account of damage to persons or property; and

(iii) Adequate insurance under all applicable workers' compensation laws.

(2) Until work under this contract has been completed and all advance payments made under the contract have been liquidated, the contractor shall--

(i) Maintain this insurance;

(ii) Maintain adequate insurance on any materials, parts, assemblies, subassemblies, supplies, equipment, and other property acquired for or allocable to this contract and subject to the Government lien under paragraph (f) of this clause; and

(iii) Furnish any evidence with respect to its insurance that the administering office may require.

(h) Default. (1) If any of the following events occur, the Government may, by written notice to the contractor, withhold further payments on this contract:

(i) Termination of this contract for a fault of the contractor.

(ii) A finding by the administering office that the contractor has failed to—

(A) Observe any of the conditions of the advance payment terms;

(B) Comply with any material term of this contract;

(C) Make progress or maintain a financial condition adequate for performance of this contract;

(D) Limit inventory allocated to this contract to reasonable requirements; or

(E) Avoid delinquency in payment of taxes or of the costs of performing this contract in the ordinary course of business.

(iii) The appointment of a trustee, receiver, or liquidator for all or a substantial part of the contractor's property, or the institution of proceedings by or against the contractor for bankruptcy, reorganization, arrangement, or liquidation.

(iv) The commission of an act of bankruptcy.

(2) If any of the events described in subparagraph (h)(1) of this clause continue for thirty days after the written notice to the contractor, the Government may take any of the following additional actions:

(i) Charge interest, in the manner prescribed in paragraph (e) of this clause, on outstanding advance payments during the period of any event described in subparagraph (h)(1) of this clause.

(ii) Demand immediate repayment by the contractor of the unliquidated balance of advance payments.

(iii) Take possession of and, with or without advertisement, sell at public or private sale all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to the sale, apply the net proceeds of the sale to reduce the unliquidated balance of advance payments or other Government claims against the contractor.

(3) The Government may take any of the actions described in subparagraphs (h)(1) and (h)(2) of this clause it considers appropriate at its discretion and without limiting any other rights of the Government.

(i) Prohibition against assignment. Notwithstanding any other terms of this contract, the contractor shall not assign this contract, any interest therein, or any claim under the contract to any party.

(j) Information and access to records. The contractor shall furnish to the administering office (1) monthly or at other intervals as required, signed or certified balance sheets and profit and loss statements, and, (2) if requested, other information concerning the operation of the contractor's business. The contractor shall provide the authorized Government representatives proper facilities for inspection of the contractor's books, records, and accounts.

(k) Other security. The terms of this contract are considered to provide adequate security to the Government for advance payments; however, if the administering office considers the security inadequate, the contractor shall furnish additional security satisfactory to the administering office, to the extent that the security is available.

(l) Representations. The contractor represents the following:

(1) The balance sheet, the profit and loss statement, and any other supporting financial statements furnished to the administering office fairly reflect the financial condition of the contractor at the date shown or the period covered, and there has been no subsequent materially adverse change in the financial condition of the contractor.

(2) No litigation or proceedings are presently pending or threatened against the contractor, except as shown in the financial statements.

(3) The contractor has disclosed all contingent liabilities, except for liability resulting from the renegotiation of defense production contracts, in the financial statements furnished to the administering office.

(4) None of the terms in this clause conflict with the authority under which the contractor is doing business or with the provision of any existing indenture or agreement of the contractor.

(5) The contractor has the power to enter into this contract and accept advance payments, and has taken all necessary action to authorize the acceptance under the terms of this contract.

(6) The assets of the contractor are not subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the contractor. There is no current assignment of claims under any contract affected by these advance payment provisions.

(7) All information furnished by the contractor to the administering office in connection with each request for advance payments is true and correct.

(8) These representations shall be continuing and shall be considered to have been repeated by the submission of each invoice for advance payments.

(m) Covenants. To the extent the Government considers it necessary while any advance payments made under this contract remain outstanding, the contractor, without the prior written consent of the administering office, shall not—

(1) Mortgage, pledge, or otherwise encumber or allow to be encumbered, any of the assets of the contractor now owned or subsequently acquired, or permit any pre-existing mortgages, liens, or other encumbrances to remain on or attach to any assets of the contractor which are allocated to performing this contract and with respect to which the Government has a lien under this contract;

(2) Sell, assign, transfer, or otherwise dispose of accounts receivable, notes, or claims for money due or to become due;

(3) Declare or pay any dividends, except dividends payable in stock of the corporation, or make any other distribution on account of any shares of its capital stock, or purchase, redeem, or otherwise acquire for value any of its stock, except as required

by sinking fund or redemption arrangements reported to the administering office incident to the establishment of these advance payment provisions;

(4) Sell, convey, or lease all or a substantial part of its assets;

(5) Acquire for value the stock or other securities of any corporation, municipality, or Governmental authority, except direct obligations of the United States;

(6) Make any advance or loan or incur any liability as guarantor, surety, or accommodation endorser for any party;

(7) Permit a writ of attachment or any similar process to be issued against its property without getting a release or bonding the property within thirty days after the entry of the writ of attachment or other process;

(8) Pay any remuneration in any form to its directors, officers, or key employees higher than rates provided in existing agreements of which notice has been given to the administering office, accrue excess remuneration without first obtaining an agreement subordinating it to all claims of the Government, or employ any person at a rate of compensation over the Salary Rate Limitation article;

(9) Change substantially the management, ownership, or control of the corporation;

(10) Merge or consolidate with any other firm or corporation, change the type of business, or engage in any transaction outside the ordinary course of the contractor's business as presently conducted;

(11) Deposit any of its funds except in a bank or trust company insured by the Federal Deposit Insurance Corporation or a credit union insured by the National Credit Union Administration;

(12) Create or incur indebtedness for advances, other than advances to be made under the terms of this contract, or for borrowings;

(13) Make or covenant for capital expenditures exceeding $ 0 total;

(14) Permit its net current assets, computed in accordance with generally accepted accounting principles, to become less than $ 0 ; or

(15) Make any payments on account of the obligations listed below, except in the manner and to the extent provided in this contract: NA.

b. FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS AND COMMERCIAL COMPONENTS (MAY 2001)

(a) **Definitions**. As used in this clause—

Commercial item has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The following clauses shall be flowed down to subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (FEB 1999) (E.O. 11246).

(iii) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APR 1998) (38 U.S.C. 4212(a)).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).

(v) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III

SECTION J—LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work dated
2. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (5/97), by reference to http://ocm.od.nih.gov/contracts/pdfs/rc1.pdf. OR
2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (5/97), by reference to http://ocm.od.nih.gov/contracts/pdfs/nihrc4.pdf
3 Privacy Act System of Records Number 09-25-0200, published in the Federal Register, Volume 64, number 229 on November 30, 1999; by reference to http://www.niaid.nih.gov/contract/privacy.pdf.
4. Procurement of Certain Equipment, NIH(RC)-7, by reference to http://ocm.od.nih.gov/contracts/rfps/nihrc7.htm.
5. Small Business Subcontracting Plan dated

PART IV

SECTION K—REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. REPRESENTATIONS AND CERTIFICATIONS

The representations and certifications at http://ocm.od.nih.gov/contracts/pdfs/rcneg.pdf must be completed, signed, and submitted as part of your business proposal. Please obtain this document as close as possible to proposal submission to ensure use of up to date clauses and provisions.

SECTION L—INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

This section of the BAA consists of the following subsections: I. Project Description, II. Specific BAA Instructions and Provisions, and III. General Instructions and Provisions.

I. PROJECT DESCRIPTION

PROJECT DESCRIPTION/RATIONALE FOR PROJECT

This Broad Agency Announcement (BAA) will establish multidisciplinary research teams. Each team will perform basic and applied research to develop novel circulatory assist devices or other bioengineered systems for infants and children with congenital and acquired cardiovascular disease who experience cardiopulmonary failure and circulatory collapse. The BAA is intended to complement and enhance ongoing NHLBI research programs in pediatric cardiovascular disease. The BAA also complements the Institute's circulatory support/artificial heart program.

STATEMENT OF WORK FOR SOLICITATION PURPOSES

Contracts awarded as a result of this BAA will incorporate the Statement of Work proposed by the offeror and negotiated and accepted by the Government. The following description of technical requirements, required objectives, and desired results will be included in the BAA to assist offerors in the preparation of their proposals.

a. General Description of the Required Objectives and Desired Results

The primary objective of this initiative is to develop novel circulatory assist devices including left and right ventricular assist devices, extracorporeal gas exchange systems, and other bioengineered systems for infants and children with congenital and acquired cardiovascular disease. Offerors are encouraged to propose basic physiological and bioengineering studies necessary for the design and evaluation of novel pediatric assist devices. This may include preclinical and clinical studies that explore innovative strategies to meet the circulatory needs of the pediatric patient population. Each offeror is expected to focus on overcoming the physiological and bioengineering hurdles that currently impede development of extracorporeal and implantable assist devices for infants and small children. Systems must be, for example, appropriately sized, but capable of providing adequate cardiac output for the infant or child, while avoiding complications associated with the patient's small size, such as vascular injury or thrombosis. It is not anticipated that every offeror will propose a program that includes clinical testing within the five contract years, although each proposal should include the design and evaluation of devices with a clear potential for future clinical application.

b. Background Information

Congenital heart disease is the most common fatal birth defect, with most deaths attributable to the inability of the heart to support adequate cardiac output. The spectrum of congenital cardiovascular malformations ranges in severity from mild to life-threatening. In addition, acquired childhood cardiac disease may result from infection, inflammation, muscle disease, or arrhythmia. In most cases, conventional medical or surgical treatment is sufficient and effective in restoring and maintaining adequate cardiac output. Some children, however, experience ventricular failure despite maximal medical and surgical management. Other infants and children could potentially benefit from circulatory support *in lieu* of prolonged high-dose positive inotropic treatment and mechanical ventilation. These children fall into the following categories, each with varying circulatory support requirements.

i. Ventricular dysfunction associated with congenital heart disease.

These children generally range in age from newborn to two years of age, although some individuals will be outside this range. Their clinical indications include the inability to separate from cardiopulmonary bypass in the operating room, intractable postoperative arrhythmia, transient ventricular dysfunction as a consequence of pre-operative anatomy and physiology, inadequate hemodynamic repair, or decreased myocardial function following prolonged cardiopulmonary bypass.

A subset of these children will have a single functional ventricle of right, left, or indeterminate ventricular morphology. Single ventricle physiology poses unique challenges for the design of circulatory support systems, and circulatory support in this setting is inadequate at present. In the normal heart, and in the hearts of most children with congenital heart disease with two functional ventricles, blood flows sequentially from the systemic circulation to the pulmonary circulation. This situation is different in children with functional single ventricle physiology where blood is simultaneously pumped to the systemic and pulmonary circulations by a single pumping chamber. Subsequent surgical procedures in these individuals require that the caval veins and their major tributaries be unobstructed. These physiological and anatomic factors need to be taken into consideration in the design of circulatory support devices for use in pediatric patients with a single functional ventricle.

ii. Ventricular dysfunction due to myocarditis, sepsis, cardiomyopathy, or cardiopulmonary collapse.

These children range in age from newborn through adolescence, and they may require prolonged circulatory support as a bridge either to myocardial recovery or to cardiac transplantation.

Key issues that affect all infants and children requiring circulatory support include the speed of initiation of ventricular support, the duration of support, the size and location of cannulation sites, exposure to blood products, and the variable range of cardiac output required based on the size of the infant or child. In some cases, such as fulminant neonatal myocarditis presenting as cardiac shock in the emergency department, rapid deployment of ventricular assist may be the difference between death and survival. Such systems are not currently available for infants and small children. In other cases, rapid deployment may be less important than the ability to sustain circulatory support with a minimum of complications while the child is awaiting recovery of cardiac function or cardiac transplantation.

In summary, this BAA seeks to support the development of a family of devices adaptable to a variety of circulatory support requirements in infants and small children. The goal is to encourage development of novel, innovative approaches to circulatory support that overcome not only the current size and hemodynamic limitations for pediatric assist devices, but that also address issues of rapid deployment, ease of use, variations in cannulation methods, and the need to minimize priming volumes, infection, bleeding, and thrombus formation.

c. Detailed Description of the Technical Requirements

1. Initiation of support: A circulatory support system should be in use less than one hour following the decision to initiate support. Often patients requiring emergent circulatory support have already experienced cardiovascular collapse and may be receiving cardiopulmonary resuscitation (CPR). Current research supports the concept that neurological

outcomes are better if adequate circulatory support is achieved rapidly. Thus, reducing the time to initiation of circulatory support is of critical importance.

Issues pertaining to the initiation of support include device availability, device priming volume, portability, and rapidity and ease of cannulation. A device should be capable of being maintained in a state of readiness so that deployment delays are minimized.

A circulatory assist device should require little or no blood to prime the circuit. Systems should be sufficiently small and portable to allow initiation of their use in the emergency room or in a patient's room where space is limited. Devices should also be designed so that patients can be easily transported to either the pediatric intensive care unit or the operating room once assist has been initiated. Insertion of cannulae should not be technically limiting so that the procedure can be performed in a variety of clinical arenas. Cannulae should be designed for secure placement to minimize the risk of being dislodged with patient movement or during transport.

2. Duration of support: Because the indications for a pediatric circulatory support device vary greatly, the duration of support required is difficult to predict. It is unlikely that one device would be applicable to all patient populations. Some patients will only require hours of support, whereas others will need the device for months until myocardial function recovers or an acceptable donor organ becomes available for transplantation.

   Device designs should include devices to provide circulatory support for up to one month, and devices that provide circulatory support for up to six months. Devices for young children requiring circulatory support for extended periods of time should be designed to be reasonably portable to optimize patient mobility and quality of life.

3. Reliability: Formal *in vitro* reliability tests, generally called "readiness testing," are not included in this BAA program. However, reliability models and device design should consider a reliability of 0.80 with 60% confidence limits as a minimum goal prior to clinical use for either the one-month or six-month system design.

4. Cannulation sites: The current extracorporeal membrane oxygenation (ECMO) circuit, when cannulated for arterial-venous circulation, requires the sacrifice of one carotid artery, potentially diminishing cerebral circulation on the cannulated side. If an offeror proposes the design of a new gas exchange assist system, novel cannulation approaches should be incorporated to preserve existing vascular anatomy.

   For the subset of patients with single ventricle anatomy who require circulatory support, device design must overcome additional barriers. Patency of the peripheral vessels used for cannulation may be essential for optimal subsequent surgical palliation. Device and cannulae design should take into account variations and limitations in the size of the patient's vasculature and the risk of central venous occlusion.

5. Infection: There are many aspects of infection control that require consideration when a circulatory assist device is employed in the pediatric patient. Whenever the skin is broken, the risk of infection rises. Although all attempts are made to place the devices as cleanly as possible, these devices are frequently placed emergently in non-operating room arenas where sterility is not always assured. The presence of indwelling cannulae increases infection rates proportional to the duration of cannulation. In addition, some patients requiring circulatory support will be relatively immunocompromised, further

increasing their risk of infection. Because of these concerns, the device designs should employ novel approaches to reduce the infection risk.

6. Exposure to blood products: Another key aspect of infection prevention is the limitation of exposure to blood products. Although the blood supply in the United States is relatively safe, there is a small risk of acquiring a blood borne infection *via* transfusion. Device designs should take into consideration limiting exposure to blood products both by decreasing the device priming volume and by limiting the need for blood sampling during the duration of support. For example, the design might incorporate self-contained monitors to determine adequacy of anticoagulation and to evaluate blood gas parameters to reduce blood sampling and the need for transfusion secondary to iatrogenic anemia.

7. Bleeding and thrombosis: Devices should incorporate strategies to minimize bleeding, hemolysis, and thrombosis. For devices to be employed in pediatric patients, this design aspect is especially critical. Blood vessels of infant brains are more susceptible to bleeding induced by shear stress. Children are also more apt to sustain injuries that could result in serious bleeding if the patient is highly anticoagulated.

8 Physiologic considerations: The most important physiologic parameter to be addressed by the circulatory support device design is adequate blood flow indexed to body size. The target body size for the family of devices would be 2 kg to 25 kg.

   Infants and small children have smaller circulating blood volumes, higher average heart rates, and smaller, more compliant blood vessels than adults. Design of devices should focus on supplying adequate flow to prevent end organ damage while limiting endothelial damage, hemolysis, and the risk of thrombus formation.

9. Evaluation of device failure: The device should be able to be routinely deployed and functioning in less than one hour. The system needs to provide adequate perfusion to maintain end organ function as assessed by blood pressure, capillary refill time, urine output, metabolic acidosis, and serum markers of end organ function. Blood gas exchange systems should provide adequate oxygenation and ventilation in the setting of cardiopulmonary collapse as evaluated by arteriolar oxygen and carbon dioxide concentrations. The system needs to function continuously for the intended period of use taking into account routine maintenance.

   During *in vitro* testing, devices need to demonstrate reliability by sustained operation for periods at least twice as long as their intended use. System outputs should not drop below minimum design flow specifications for a period exceeding five minutes for each hour of operation. During clinical use, flow variations must not result in significant clinical adverse events.

10. Other design considerations: Audible noise and vibration must be acceptable to patients, family members, and medical personnel. Devices must be reliable in any orientation of the patient. Issues of electromagnetic field generation and susceptibility to energy fields must be addressed.

    Offerors may submit a proposal for research that addresses only one or both of the two patient need categories described above in item (b). Thus, designs that address only short term needs (up to one month), or only longer term needs (up to six months), as well as devices that may fulfill both short and longer term design requirements, will be considered responsive to this announcement.

d. Reference Material

Reference will be cited in the BAA to the *National Heart, Lung, and Blood Institute Task Force on Research in Pediatric Cardiovascular Disease* (May 2002) at http://www.nhlbi.nih.gov/resources/docs/pediatric_cvd.htm.

e. Phasing

Phasing may be applicable for some or all of the proposals submitted in response to this solicitation. The announcement requires offerors to include time-phased schedules in their proposals. Program plans are required by this solicitation and will be updated annually.

f. Clinical Research/Human or Animal Subjects

Because devices suitable for testing in humans or animals may be proposed in response to this announcement, offerors must refer to the appropriate policy statements at http://www.nhlbi.nih.gov/funding/policies/index.htm.

Animal Care and Use—The Contractor shall obtain, prior to the start of any work under this contract involving animals, an approved Animal Welfare Assurance from the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance. Refer to http://grants.nih.gov/grants/olaw/references/phspol.htm.

Under governing policy, federal funds administered by the Public Health Service (PHS) shall not be expended for research involving live vertebrate animals without prior approval by the office of laboratory animal welfare (OLAW), of an assurance to comply with the PHS policy on humane care and use of laboratory animals. This restriction applies to all performance sites (e.g. collaborating institutions, subcontractors, subgrantees) without OLAW-approved assurances, whether domestic or foreign.

Many proposals are expected that will not involve testing of devices in human beings; it is possible that some proposals will involve human testing. All proposed devices that are successful will be subjected to extensive animal and human testing whether during the contract period or after contract completion, as necessary to receive FDA approval for sales and use. The above references are considered to be potentially valuable to offerors regardless whether they are required to be included in any particular contract.

g. Special Requirements (as applicable)

Geographic limitations are specifically not anticipated for this solicitation; full and open competition is anticipated for offers both foreign and domestic.

II. SPECIFIC BAA INSTRUCTIONS AND PROVISIONS

The following specific BAA instructions and provisions apply to this Broad Agency Announcement:

A. Proposal Intent Response Sheet (submit prior to proposal submission—by March 21, 2003)

B. Packaging and Delivery of Proposal

A. PROPOSAL INTENT RESPONSE SHEET

BAA No. NHLBI-HV-04-01

TITLE OF BAA: Pediatric Circulatory Support

If you intend to submit a proposal, please FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY **March 21, 2003.** YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

COMPANY/INSTITUTION NAME:

ADDRESS:

PROJECT DIRECTOR'S NAME:

TITLE:

TELEPHONE NUMBER:

NAMES OF COLLABORATING INSTITUTIONS AND INVESTIGATORS
(include Subcontractors and Consultants):

RETURN TO:

Review Branch
NIH, NHLBI
Attention: Anne Clark FAX (301) 480-0730
6701 ROCKLEDGE DR MSC 7924
BETHESDA MD 20892-7924

B. PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in the "Standard RFP Instructions and Provisions." Shipment and marking shall be as follows:

EXTERNAL PACKAGE MARKING
In addition to the address cited below, mark each package as follows:

"BAA NO. NHLBI-HV-04-01
"TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

The numbers of copies required of each part of your proposal are:
TECHNICAL PROPOSAL: ORIGINAL* AND Twenty-five (25) COPIES
BUSINESS PROPOSAL: ORIGINAL* AND Six (6) COPIES

DELIVER PROPOSAL TO:

Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute, NIH
Rockledge 2, Room 7091
6701 ROCKLEDGE DR MSC 7924
BETHESDA MD 20892-7924

Due to post 9/11 security measures, DELIVERIES WILL ONLY BE ACCEPTED BY US POSTAL SERVICE OR COMMERCIAL COURIER SERVICES SUCH AS UPS, FEDEX, HDL, ETC. Proposals delivered in person may or may not be accepted.

*THE ORIGINAL PROPOSAL MUST BE READILY ACCESSIBLE FOR DATE STAMPING. IN ADDITION, EVERY SEPARATELY BOUND VOLUME MUST CONTAIN THE ORGANIZATION'S NAME, ADDRESS, AND BAA NUMBER

III. GENERAL INSTRUCTIONS AND PROVISIONS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS—COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) Definitions. As used in this provision—

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing," "writing," or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals. (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show—

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and—

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation,

as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror). [Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) Restriction on disclosure and use of data. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(g) Contract award. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;

(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iii) A summary of the rationale for award; and

(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this BAA), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that four to eight awards will be made from this solicitation and that the awards will be made on/about February 15, 2004.

It is anticipated that the awards from this solicitation will be multiple-year cost reimbursement type completion form contracts with terms of five years and that incremental funding will be used [see Business Proposal Instructions, Item I.8 on web].

e. ESTIMATE OF EFFORT

It is expected that completion form contracts will be awarded as a result of this BAA. The Government does not intend to provide an estimate of effort for this BAA.

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this BAA. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in Section M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. PREPARATION COSTS

This BAA does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (AUGUST 1996) FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Robert A. Julia, Contracting Officer
National Institutes of Health
National Heart, Lung, and Blood Institute
Contracts Operations Branch
Rockledge 2, Room 6110
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

l. AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington DC 20402.

m. GOVERNMENT FURNISHED FACILITIES AND EQUIPMENT

No materials, facilities, or property are anticipated to be provided by the Government for this acquisition.

2. INSTRUCTIONS TO OFFERORS

The instructions set forth below are provided by URL links to "Streamlined RFP" instructions which are considered a part of this solicitation, including the required forms and formats. (Note that in some cases, versions of forms that can be filled out on screen may be available at http://forms.cit.nih.gov/ListPDF.html.) In the event of a conflict between the instructions written in

this document and the Streamlined RFP instructions on the Web, the former take precedence. In the event of conflict between the general and special instructions on the Web, the latter take precedence.

a. GENERAL INSTRUCTIONS

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. Note that the Instructions to Offerors (Items A through F at the link below) are superseded by Section II part 1. above, http://ocm.od.nih.gov/contracts/rfps/inststd.htm#Instructions—General.

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks. See instructions at: http://ocm.od.nih.gov/contracts/rfps/inststd.htm#Instructions—Technical

TECHNICAL PROPOSAL TABLE OF CONTENTS

Please number each page of text. Type density and size must be 10-12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch.

The technical proposal should be organized as follows:

1. TECHNICAL PROPOSAL COVER SHEET (Form is located in the Streamlined RFP References under "FORMS, FORMATS, ATTACHMENTS ") . . . . Page 1

2. TECHNICAL PROPOSAL TABLE OF CONTENTS . . . . . Page 2

3. ABSTRACT . . . . . Page 3
State the proposal's broad, long-term objectives and specific aims. Briefly and concisely describe the research design and methods for achieving these goals. DO NOT EXCEED one page in providing the abstract. Identify the BAA Number, Institution and Principal Investigator on the abstract.

4. TECHNICAL APPROACH (no more than 36 PAGES single-spaced)
Refer to Technical Proposal Instructions located in the Standard RFP Instructions and Provisions under Streamlined RFP References for more detail.

A. PERSONNEL

(1) List of all Personnel in the project including Subcontractors, Consultants/Collaborators, by name, title, department and organization . . . . . Page #

PROVIDE NARRATIVE FOR:

(2) Principal Investigator/Project Director . . . . . Page #

(3) Other Investigators . . . . . Page #

(4) Additional Personnel . . . . . Page #
[NOTE: For personnel, include a two-page biosketch under APPENDICES below.]

B. WORK STATEMENT

(1) Objectives . . . . . Page #

(2) Approach . . . . . Page #

(3) Methods . . . . . Page #

(4) Schedule . . . . . Page #

C. FACILITIES, EQUIPMENT, AND OTHER RESOURCES . . . . . Page #

List/describe all facilities, equipment and other resources available for this project.

D. OTHER CONSIDERATIONS . . . . . Page #
(Use specifically titled subparagraphs, as applicable.)

5. OTHER SUPPORT . . . . . Page #

Complete the Form "Summary of Current and Proposed Activities." All key personnel must be listed on this form. The form is located in the Streamlined RFP References under "FORMS, FORMATS, ATTACHMENTS."

6. TECHNICAL PROPOSAL COST INFORMATION . . . . . Page #

(Form is located in the Streamlined RFP References under "FORMS, FORMATS, & ATTACHMENTS.")

7. LITERATURE CITED . . . . . Page #

8. APPENDICES . . . . . Page #

Total number of appendices shall not exceed 50 pages single-spaced. List each Appendix and identify the number of pages for each one. Appendices must be clear and legible, and easily located. Include biosketches here.

PAGE LIMITS

The Technical Plan (objectives, approach, methods and procedures, and schedule) of the Technical Proposal shall not exceed 36 single-sided pages or 18 double-sided pages. This page limitation does not apply to the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, other support, cost information, and literature cited. Appendices shall be limited to 50 single-sided pages or 25 double-sided pages. Pages in excess of this will be deleted and will be neither read nor evaluated. Each page of the Technical Proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around, exclusive of headers or footers.

c. BUSINESS PROPOSAL INSTRUCTIONS

See: http://ocm.od.nih.gov/contracts/rfps/instst d.htm#Instructions—Business

Note: The "pre-formatted cost proposal spreadsheet" referenced and linked therein should be used and should be provided to the Contracting Officer on disk or CD or by email. Click for the pre-formatted cost proposal spreadsheet. [Note: This is an Excel spreadsheet that will work with other spreadsheet software.] This solicitation may require submission of certified cost or pricing data.

The following solicitation provisions supersede equivalent language on the referenced instruction page:

1. Small Disadvantaged Business Participation Plan

In accordance with FAR part 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized SIC Major Groups will be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

[NOTE: The SDB Participation Plan is a separate requirement from the Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan described elsewhere in this solicitation, if applicable. Offerors shall submit a Small Disadvantaged Business Participation Plan which includes the following information in one clearly marked section of their business proposal:]

A plan on the extent of participation of SDB concerns in performance of the contract. Participation in performance of the contract includes the work expected to be performed by SDB concern(s). This can include SDB (as prime contractor), joint ventures, teaming arrangements, and subcontracts. Include the following information in your SDB participation plans:

a. The extent of an offerors commitment to use SDB concerns. Commitment should be as specific as possible, e.g., are subcontract arrangements already in place; are letters of commitment in place. Enforceable commitments will be weighted more heavily than non-enforceable ones;

b. Specifically identify the SDB concerns with point of contact and telephone number;

c. The complexity and variety of the work SDB concerns are to perform;.

d. Realism for the use of SDB in the proposal;

e. Past performance of the offeror in complying with subcontracting plans for SDB concerns;

f. Targets expressed as dollars and percentage of total contract value, in each of the applicable authorized SIC Major Group(s). A total target for SDB participation by

the prime contractor that includes any joint ventures and team members* shall be provided, as well as a total target for SDB participation by subcontractors. Targets may be incorporated into and become part of any resulting contract; and

g. The extent of participation of SDB concerns in terms of the value of the total acquisition.

*[*NOTE: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors].*

SDB participation information furnished in the plan described above will not be used as an evaluation factor (Section M—Evaluation Factors for Award). The Government will focus on information that demonstrates realistic commitments to use SDB concerns relative to the size and complexity of the acquisition under consideration. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's commitment to SDB participation.

The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor. The assessment of the offeror's SDB Participation Plan will be used as a means of evaluating the relative capability and commitment of the offeror and the other competitors, e.g., an offeror with an exceptional record of participation with SDB concerns may receive a more favorable evaluation than another whose record of participation with SDB concerns is acceptable, even though both may have acceptable technical proposals.

[NOTE: Offers to rely on SDB concerns merely for such activities as provision of supplies and basic services such as travel arrangements, unless such supplies and arrangements are of significant value and are an integral part of contract performance, will be considered of negligible value for the purposes of evaluating the SDB participation plan.]

2. Uniform Resource Locators (URLs) in Contract Proposals

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

3. Past Performance Information

a. Offerors shall submit the following information as part of their business proposals (for both the offeror and proposed major subcontractors): A list of the contracts completed during the past three years and all contracts currently in progress for products or services similar to the solicitation workscope. Contracts listed may include those entered into with the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel. Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Project Officer's Name and Telephone Number

b. Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. Performance information will be used for responsibility determinations. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. The Government is not required to contact all references provided by the offeror, References other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of an offeror's past performance.

4. FOREIGN R&D PROPOSALS

If a foreign R&D proposal is received, the peer review group will address the need or appropriateness of accomplishing the work overseas.

5. EVALUATION OF FOREIGN CURRENCY OFFERS, FAR 52.225-17, (FEBRUARY 2000)

If the Government receives offers in more than one currency, the Government will evaluate offers by converting the foreign currency to United States currency using currency exchange rates reported in *The Washington Post* in effect as follows:

(a) For acquisitions conducted using sealed bidding procedures, on the date of bid opening.

(b) For acquisitions conducted using negotiation procedures—

(1) On the date specified for receipt of offers, if award is based on initial offers; otherwise

(2) On the date specified for receipt of proposal revisions

SECTION M—EVALUATION FACTORS FOR AWARD

1. GENERAL

The Government will make awards to the responsible offerors whose proposals provide the best value to the Government. For this solicitation, technical proposal, importance to agency programs, and fund availability will receive paramount consideration in the selection of contractors for this acquisition. Past performance will be evaluated as a "stand-alone factor" independent of the technical evaluation. Evaluation of Small Disadvantaged Business (SDB) Participation Plans will be made based on a consideration of all relevant facts and circumstances, not on absolute standards of acceptable performance. The Government is seeking to determine whether

the offeror has demonstrated its commitment and capability to use SDB concerns for the work that it intends to perform as the prime contractor. Evaluation of the plan will be performed only on those offers being considered for award. SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation Plan will be considered in determining the relative merits of the offeror's proposal. All evaluation factors other than cost/price, when combined, are significantly more important than cost/price. The trade-off process described in FAR 15.101-1 will be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective offerors in relation to the evaluation criteria as set forth herein and the project needs as set forth in the BAA. Each proposal must document the feasibility of successful implementation of the requirements of the BAA. The estimated cost of an offer must be reasonable for the tasks to be performed, and in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government. The merits of each proposal will be evaluated carefully, based on responsiveness to the BAA and the thoroughness and feasibility of the technical approach proposed. The technical evaluation of proposals will be conducted through a peer or scientific review process in accordance with established criteria set forth below.

NHLBI program and administrative staff will determine importance to agency programs and availability of funds. Final selection of awards will depend upon scientific merit, the proposed costs in relation to availability of funds, and program balance within the NHLBI at the time of award selection. The NHLBI reserves the right to select a variety of technical approaches.

2. The technical review criteria and weighting factors to be used to evaluate technical proposals submitted in response to this solicitation are:

No.	Criterion	Points
1.	**Concept and Theory**—Potential for the proposed concept to result in the development of a pediatric circulatory support system that meets clinical and performance goals. The degree to which design, potential design challenges, biocompatibility, modeling, and quality control tasks are identified and addressed.	**25**
2.	**Innovation**—The degree to which the proposed concepts are innovative relative to existing systems.	**20**
3.	**Research, Design, Development, and Manufacturing**—The appropriateness of the proposed research to implement concepts for a new pediatric circulatory support system. The degree to which design controls, fabrication, manufacturability, and quality control of the device are addressed.	**20**
4.	**Plan for Testing and Evaluation**—The adequacy and appropriateness of component testing and/or whole device testing *in vitro* and *in vivo*, including pathology and explant studies and justification of an appropriate animal model.	**20**
5.	**Capabilities of Offeror**—The degree to which the offeror has the necessary expertise and commitment, facilities, and resources to accomplish the goals of the BAA.	**15**
		Total: 100