SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
▶		1 of 37

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	RFP NHLBI-HV-98-24	☐ SEALED BID (IFB) ☑ NEGOTIATED (RFP)	8/11/98	

7. ISSUED BY	CODE	8. ADDRESS OFFER TO *(If other than Item 7)*
National Heart, Lung, & Blood Institute, NIH Rockledge2, Room 6112 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902		Review Branch, Division of Extramural Affairs National Heart, Lung, and Blood Institute, NIH Rockledge Building, 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 handcarried, in the depository located in [Block 8] *But see p. 17 until 4:30 pm *(Hour)* local time 12/01/1998 *(Date)*

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)* AREA CODE	NUMBER	EXT.	C. E-MAIL ADDRESS
	Sharon M. Kraft	301	435-0340	NA	sk40f@nih.gov

(✓)	SEC.	PART I -- THE SCHEDULE		(✓)	SEC.	PART II -- CONTRACT CLAUSES	
		11. TABLE OF CONTENTS					
✓	A	SOLICITATION/CONTRACT FORM	1	✓	I	CONTRACT CLAUSES	10-14
✓	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2-3			PART III -- LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
✓	C	DESCRIPTION/SPECS./WORK STATEMENT	3-6	✓	J	LIST OF ATTACHMENTS	14
✓	D	PACKAGING AND MARKING	6			PART IV -- REPRESENTATIONS AND INSTRUCTIONS	
✓	E	INSPECTION AND ACCEPTANCE	7	✓	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	15
✓	F	DELIVERIES OR PERFORMANCE	7-8				
✓	G	CONTRACT ADMINISTRATION DATA	8-9	✓	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	15-36
✓	H	SPECIAL CONTRACT REQUIREMENTS	9-10	✓	M	EVALUATION FACTORS FOR AWARD	36-37

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 305 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 amend-ments 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.

SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this program is to conduct a randomized trial comparing the efficacy of Pulmonary Artery Catherization (PAC)-directed treatment strategy to a treatment strategy without the use of PAC on morbidity and mortality in patients with **New York Heart Association (NYHA) Class IV Congestive Heart Failure (CHF)**. The hypothesis being tested is that for patients admitted with persistent symptoms of CHF at rest or with minimal exertion, therapy tailored using hemodynamic monitoring results in a better clinical outcome than current standard therapy without invasive monitoring. The information provided by this multicenter collaborative clinical trial may provide a rational basis for safe and effective therapy for patients with severe CHF. Furthermore, the results may have significant health care cost implications.

ARTICLE B.2. PRICES/COSTS

a. The contractor shall be paid by the Government in accordance with the following schedule in response to monthly invoices of actual quantities and amounts, only when all deliverables and functions are accepted.

Item	Description	Qty	Unit Price ($)	Total
1.	Randomization	222	X$	222X$
2.	Discharge	222	X$	222X$
3.	Followup V.1	203	X$	203X$
4.	Followup V.2	184	X$	184X$
5.	Followup V.3	165	X$	165X$
6.	Followup V.4	128	X$	128X$
			Total Funded Amount	1124X$

b. The prices set forth in this ARTICLE B.2. will cover the contract period September 1, 1999 through August 31, 2000.

c. In the event of exercise of option 1, the payment schedule in paragraph a shall be amended to read as follows for the contract period September 1, 2000 through August 31, 2001:

Item	Description	Qty	Unit Price ($)	Total
1.	Randomization	222	X$	222X$
2.	Discharge	222	X$	222X$
3.	Followup V.1	222	X$	222X$
4.	Followup V.2	221	X$	221X$
5.	Followup V.3	221	X$	221X$
6.	Followup V.4	219	X$	219X$
			Total Funded Amount	1327X$

d. In the event of exercise of option 2, the payment schedule in paragraph a shall be amended to read as follows for the contract period September 1, 2001 through April 30, 2002:

Item	Description	Qty	Unit Price ($)	Total
1.	Randomization	56	X$	56X$
2.	Discharge	56	X$	56X$
3.	Followup V.1	74	X$	74X$
4.	Followup V.2	92	X$	92X$
5.	Followup V.3	110	X$	110X$
6.	Followup V.4	146	X$	146X$
			Total Funded Amount	534X$

e. In the event of exercise of option 3, the payment schedule in paragraph a shall be amended to read as follows for the contract period May 1, 2002 through February 28,2003:

Item	Description	Qty	Unit Price ($)	Total
1.	Monthly Report	1	X$	X$
2.	Monthly Report	1	X$	X$
3.	Monthly Report	1	X$	X$
4.	Monthly Report	1	X$	X$
5.	Monthly Report	1	X$	X$
6.	Monthly Report	1	X$	X$
7.	Monthly Report	1	X$	X$
8.	Monthly Report	1	X$	X$
9.	Monthly Report	1	X$	X$
10.	Final Report	1	X$	X$
			Total Funded Amount	10X$

SECTION C—DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

(For a complete description of the Background and History, Statement of Work, and explanations of initials and acronyms, including study design requirements and considerations, refer to IV, Project Information, in Section L below.)

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 the work below. Specifically, the contractor shall:

1. Provide the study protocol, Manual of Operations, and data gathering forms.

2. Provide a recruitment plan and document the ability to recruit a minimum of 500 patients. Criteria for selection of the Clinical Coordinating Network Center (CCNC) shall at a minimum

include evidence of adequate patient population and evidence of medical and lay community support.

3. Provide IRB clearances and assurances from all participants within the CCNC network.

4. Provide a plan documenting the ability to carry out uniform data entry and collection from all participating units within the network.

5. Provide a plan documenting the ability to carry out the protocol uniformly, including protocol implementation and standardization and staff training, at all recruitment sites.

6. Have in place a random assignment system for patient entry into the ESCAPE trial at each clinical unit.

7. Provide a plan for monitoring patient recruitment reports during the recruitment period. This report shall specifically include data on recruitment of women and specific minorities (targeting 50% of women and 20% of minorities, such as African Americans, Hispanic, Native American, Asian). It is anticipated that site visits to clinical units will be necessary to assure recruitment and monitor the quality of data (e.g., one visit a year to approximately 10 clinical units during the recruitment phase). Assume the primary responsibility for evaluating and correcting problems, including certification of new clinical units, termination of recruitment at existing sites, and appropriate follow-up of patients enrolled from the terminated site.

8. Provide a plan to maintain appropriate data files and maintain appropriate confidentiality and security of these files.

9. Provide a plan for monitoring performance and have quality control measures in place for both clinical units and central units.

10. Provide a plan for performing the following measurements in all patients:

    A. Echocardiogram during the index hospitalization and at 6 month follow-up, as a part of the routine medical care.

    B. Circulating levels of neuro/natriuretic peptides, such as pro-ANP, at baseline, discharge, and 6 month follow up.

11. Provide a plan for monitoring quality control and status of performance of the clinical sites and prepare reports on these and related matters at regular intervals. Assume responsibility to review, on a regular basis, the quality of all data transmitted by the clinical sites.

12. Provide a plan for appropriate methods of analysis and presentation of data collected during the course of the study.

13. Provide a plan for interim technical and statistical reports for the periodic communications within the CCNC network.

14. Provide a plan for establishing a Morbidity and Mortality Classification Committee (MMCC) and for organization of review to classify major clinical events of the study and fund all related expenses.

15. Provide a plan for arranging and funding of the DSMB activities (anticipated one meeting a year for 4 members and semiannual conference calls). Provide interim technical and statistical reports for presentation to the DSMB.

16. Provide a plan for coordination and arrangement of, and participate in and provide any information necessary for, Steering Committee or other clinical investigator meetings and prepare and distribute minutes of each meeting and any other correspondence necessary, in a timely manner.

17. Provide a plan for evaluating the knowledge of the team participating in the study at the baseline and at the end of the study.

18. Provide a plan for close monitoring of adverse events to maximize patient safety. In cases of major adverse events (death, cardiopulmonary arrest, emergent cardiopulmonary interventional procedures) the contractor shall notify the Program Office and prepare a report to the Program Office and DSMB no later than 48 hours after being informed of the event.

19. Assume the responsibility for preparing study data for publication in collaboration with the investigators and the NHLBI Program Office.

OPTIONAL ACTIVITIES

The offeror may consider any of the following activities:

1. Echocardiogram at discharge.

2. In relation to the performance of central interpretation of echo cardiographic data activities the contractor shall:

   A. Specify standardized methods for proper data collection, handling, and analysis in a manner that assures validity of results. This includes quality control measures at clinical units and the central lab.

   B. Provide quality control measures for performance and data collecting, such as verification of data entered and analyzed.

3. Exercise test with VO2 measurement on admission and at 6 month follow up.

4. Have a plan for evaluation of knowledge related to PAC monitoring at the baseline and after the protocol implementation.

The Background and History and Statement of Work in Part IV, Project Information, and the Protocol and Manual of Operations submitted by the offeror and accepted by the Government, shall be incorporated herein and considered a part of the Statement of Work.

ARTICLE C.2. REPORTING REQUIREMENTS

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 below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

(a) Weekly Enrollment Reports

Numbers of patients recruited from each clinical unit and aggregate data, including recruitment of minorities and women. Those patients eligible for randomization but refusing to participate should also be tabulated.

(b) Monthly Technical Progress Report upon completion of followup

This report shall include a description of the progress of analyses and publications in process for the final option period following completion of the study followup period. The first such report shall be due May 31, 2002. Thereafter, reports shall be due on or before the last day of each month of performance, except that the monthly report will not be required for the final month of the contract when the final technical progress report is due. Payment of monthly invoices during this period shall depend on acceptance of the monthly technical progress report.

(c) Final Report

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period in accordance with ARTICLE F.1, DELIVERIES, of this contract.

(d) Summary of Salient Results

The contractor shall submit with the Final Report a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

(e) Minutes of Data Safety and Monitoring Board (DSMB)

Minutes of each meeting will be submitted to the Project Office within 15 calendar days following the meeting.

(f) Minutes of Steering Committee Meetings

Minutes of each meeting will be submitted to the Project Office within 15 calendar days following the meeting.

(g) Core Lab Reports

This report shall document the monthly performance (data received and analyzed) from the core lab throughout the study.

(h) Data Tapes

Data Tapes and documentation shall be delivered on the contract expiration date.

SECTION D—PACKAGING, MARKING, AND SHIPPING

The Contractor shall guarantee that all required materials, such as pathology samples, 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 and/or at the Contractor's site. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days following delivery (performance) of medical/surgical services. Primary evidence of acceptance of services will be payment by the Government of amounts invoiced for each.

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.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:
52.246-4, INSPECTION OF SERVICES—FIXED PRICE.

SECTION F—DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the services described in this contract shall be from September 1, 1999 through August 31, 2000 (and through February 28, 2003 if all options are exercised), as follows:

YEAR	OPTION PERIOD
Base Year	September 1, 1999 through August 31, 2000
Option Year 1	September 1, 2000 through August 31, 2001
Option Year 2	September 1, 2001 through April 30, 2002
Option Year 3	May 1, 2002 through February 28, 2003

ARTICLE F.2. DELIVERABLES

a. Satisfactory performance of this contract shall be deemed to occur upon completion of the services described in ARTICLE C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

Item	Description	Delivered to:	Delivery Schedule
a.	Weekly Enrollment Reports	Project Officer and Contracting Officer	Weekly during recruitment phase
b.	Monthly Progress Report in Phase II	Project Officer and Contracting Officer	Monthly upon completion of followup
c.	Final Report	Project Officer and Contracting Officer	Upon completion of the contract

Item	Description	Delivered to:	Delivery Schedule
d.	Summary of Salient Results	Project Officer	Upon completion of the contract
e.	Minutes of DSMB	Project Officer and Contracting Officer	15 calendar days following the meeting
f.	Minutes of Steering Committee Meetings	Project Officer and Contracting Officer	15 calendar days following the meeting
g.	Core Laboratory	Project Officer and Contracting Officer	Monthly
h.	Data Tapes	Project Officer	Upon contract completion date

Copies of reports shall be sent to the following addresses:

Addressee	Item	Quantity
Project Officers Heart Research Program, DHVD, NHLBI 6701 ROCKLEDGE DR MSC 7940 BETHESDA MD 20892-7956	(a)-(h)	2 each
Contracting Officer	(a)-(c)	1 each
Contracts Operations Branch, DEA, NHLBI 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902	(e)-(g)	1 each
Steering Committee Meeting (List to be developed)	(f)	1 each

SECTION G—CONTRACT ADMINISTRATION DATA

ARTICLE G.1. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME	TITLE
[To be inserted]	[To be inserted]
[To be inserted]	[To be inserted]

ARTICLE G.2. PROJECT OFFICER

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

[To be inserted]

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 Government may unilaterally change its Project Officer designation.

ARTICLE G.3. INVOICE SUBMISSION

Invoice Instructions for NIH Fixed-Price-Type Contracts, NIH(RC)-2, are attached and made part of this contract. The invoice instructions and the following directions for the submission of invoices must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9.

a. Invoices shall be submitted concurrently as follows:

An original and two copies to the following approving officer:

Contracting Officer
HLVD Contracts Section, COB
National Heart, Lung, and Blood Institute, NIH
Rockledge 2 Room 6112
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

b. Inquiries regarding payment of invoices should be directed to the designated payment office, attention of Chief, Contract Accounting Section, DEFS (301) 496-6452.

SECTION H—SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the NHLBI, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the Optional Form 310.

ARTICLE H. 2,. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)

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.3. OPTION PROVISION

a. Unless the Government exercises its option pursuant to paragraph b. of this article, the contract consists only of Year 1 of the statement of work as defined in Sections C and F of this contract. Pursuant to clause 52.217-8 set forth in paragraph b. below, the Government may, by unilateral contract modification, require the Contractor to perform Options 1-3 of the statement of work as also defined in Sections C and F of this contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in Article B.2.

b. 52.217-8, OPTION TO EXTEND SERVICES (AUGUST 1989). The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 54 months. The Contracting Officer may exercise the option by written notice to the Contractor within the period specified in the Schedule.

(End of Clause)

PART II, CONTRACT CLAUSES

(NOTE: The following section would normally be among the General Clause Listings at http://rcb.nci.nih.gov/Clauses/Clauses.html, but the full text is incorporated below because that web page is currently blank at the time of construction of this document.)

SECTION I—CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT—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 full text. Upon request, the Contracting Officer will make their full text available [FAR 52.252-2 (JUN 1988), Alternate I (JUN 1988)].

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

FAR CLAUSE NO.	TITLE AND DATE
52.202-1	Definitions (OCTOBER 1995)
52.203-3	Gratuities (Over $100,000) (APRIL 1984)
52.203-5	Covenant Against Contingent Fees (Over $100,000) (APRIL 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (Over $100,000) (JULY 1995)
52.203-7	Anti-Kickback Procedures (Over $100,000) (JULY 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000) (JANUARY 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000) (SEPTEMBER 1990)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000) (JUNE 1997)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (Over $100,000) (Over $100,000) (JUNE 1996)
52.209-6	Protecting the Government's Interests when Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000) (JULY 1995)
52.215-2	Audit and Records—Negotiation (Over $100,000) (AUGUST 1996)
52.215-8	Order of Precedence—Uniform Contract Format (OCTOBER 1997)
52.215-10	Price and Records—Negotiation (Over $100,000) (AUGUST 1996)
52.215-12	Subcontractor Cost or Pricing Data (Over $500,000) (OCTOBER 1997)
52.215-14	Integrity of Unit Prices (Over $100,000) (OCTOBER 1997)
52.215-15	Termination of Defined Benefit Pension Plans (OCTOBER 1997)
52.215-18	Reversion of Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions (OCTOBER 1997)
52.215-19	Notification of Ownership Changes (OCTOBER 1997)
52.215-21	Requirements for Cost of Pricing Data or Information Other than Cost or Pricing Data—Modifications (OCTOBER 1997)
52.219-8	Utilization of Small, Small Disadvantaged, and Women-Owned Small Business Concerns (Over $100,000) (JUNE 1997)
52.2 19-9	Small, Small Disadvantaged, and Women-Owned Small Business Subcontracting Program (Over $500,000) (AUGUST 1996)
52.219-16	Liquidated Damages—Subcontracting Plan (OCTOBER 1995)
52.222-3	Convict Labor (AUGUST 1996)
52.222-26	Equal Opportunity (APRIL 1984)

FAR CLAUSE NO.	TITLE AND DATE
52.222-28	Equal Opportunity Preaward Clearance of Subcontracts (over $1,000,000) (APRIL 1984)
52.222-35	Affirmative Action for Special Disabled and Vietnam Era Veterans (APRIL 1998)
52.222-36	Affirmative Action for Handicapped Workers (JUNE 1998)
52.222-37	Employment Reports on Special Disabled Veterans and Veterans of the Vietnam Era (APRIL 1998)
52.223-2	Clean Air and Water (Over $100,000) (APRIL 1984)
52.223-6	Drug Free Workplace (JANUARY 1997)
52.223-14	Toxic Chemical Release Reporting (OCTOBER 1996)
52.225-3	Buy American Act—Supplies (JANUARY 1994)
52.225-11	Restrictions on Certain Foreign Purchases (OCTOBER 1996)
52.227-1	Authorization and Consent (Over $50,000) (JULY 1995); Alternate I (APRIL 1984)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000) (AUGUST 1996)
52.227-11	Patent Rights—Retention by the Contractor (Short Form) (JUNE 1997) 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.
52.229-3	Federal, State, and Local Taxes (Over $100,000) (JANUARY 1991)
52.229-5	Taxes—Contracts Performed in U.S. Possessions or Puerto Rico (APRIL 1984)
52.232-2	Payments Under Fixed Price Research and Development Contracts (APRIL 1984)
52.232-8	Discounts for Prompt Payment (APRIL 1989)
52.232-9	Limitation on Withholding of Payments (APRIL 1984)
52.232-11	Extras (APRIL 1984)
52.232-17	Interest (Over $100,000) (JUNE 1996)
52.232-18	Availability of Funds (APRIL 1984)
52.232-23	Assignment of Claims (JANUARY 1986)
52.232-25	Prompt Payment (JUNE 1997)
52.232-33	Mandatory Information for Electronic Funds Transfer Payment Methods (AUGUST 1996)
52.233-1	Disputes (OCTOBER 1995)
52.233-3	Protest After Award (AUGUST 1996)
52.242-13	Bankruptcy (Over $100,000) (JULY 1995)

FAR CLAUSE NO.	TITLE AND DATE
52.243-1	Changes—Fixed Price (AUGUST 1987); Alternate V (APRIL 1984)
52.244-1	Subcontracts (Fixed-Price Contracts) (OCTOBER 1997) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B.3., Advance Understandings.
52.245-2	Government Property (Fixed Price Contracts) (DECEMBER 1989)
52.246-23	Limitation of Liability (Over $100,000) (FEBRUARY 1997)
52.246-25	Limitation of Liability—Services (APRIL 1984)
52.249-2	Termination for Convenience of the Government (Fixed-Price) (SEPTEMBER 1996)
52.249-5	Termination for Convenience of the Government (Educational and other Nonprofit Institutions) (SEPTEMBER 1996)
52.249-9	Default (Fixed-Price Research and Development) (Over $100,000) (APRIL 1984)
52.253-1	Computer Generated Forms (JANUARY 1991)

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

HHSAR CLAUSE NO.	TITLE AND DATE
352.202-1	Definitions (APRIL 1984)
352.232-9	Withholding of Contract Payments (APRIL 1984)
352.270-4	Pricing of Adjustments (APRIL 1984)
352.270-6	Publication and Publicity (JULY 1991)
352.270-7	Paperwork Reduction Act (APRIL 1984)

[END of GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT.]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

The following clause(s) are part of this contract:

a. FAR clause 52.215-26, Alternate I (APRIL 1991) is added to FAR clause 52.215-26, INTEGRITY OF UNIT PRICES (APRIL 1991)

b. FAR Clause no. 52.215-27, TERMINATION OF DEFINED BENEFIT PENSION PLANS (MARCH 1996), is deleted in its entirety.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following 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.

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

(1) FAR 52.203-12, Limitation on Payments to Influence Certain Federal Transactions (JANUARY 1990)

(2) FAR 52.217-9, Option to Extend the Term of the Contract (March 1989). The full text of this clause, including insertions, is as follows:

> (a) The Government may extend the term of this contract by written notice to the Contractor within the time specified in the Schedule; *provided*, that the Government shall give the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.
>
> (b) If the Government exercises this option, the extended contract shall be considered to include this option provision.
>
> (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed forty two (42) months.
>
> (End of clause)

(3) FAR 52.219-14, Limitation on Subcontracting (JANUARY 1991)

(4) FAR 52.227-14, Rights in Data—General (JUNE 1987)

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

< None >

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

The following clause is attached and will be made a part of any contract resulting from this RFP.

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

PART III—LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J—LIST OF ATTACHMENTS

See listing of RFP and Contract attachments in Section L below.

PART IV—REPRESENTATIONS AND INSTRUCTIONS

SECTION K—REPRESENTATIONS AND CERTIFICATIONS

The Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated) for this RFP are attached at the end of this document. The web page does not contain the version needed for negotiated fixed research and development contracts. Please see also the instructions for the attached form in the listing of RFP and Contract attachments in Section L below.

SECTION L—INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

THIS SECTION OF THE RFP CONSISTS OF THE FOLLOWING SECTIONS:

II. Specific RFP Instructions and Provisions,

III. Applicable RFP References, and

IV. Project Information

II. SPECIFIC RFP INSTRUCTIONS AND PROVISIONS

NOTICE TO OFFERORS: This section contains proposal instructions and information which are specifically related to this acquisition. The information provided below is only a portion of the instructions and notices required for the submission of a proposal. References to additional, more general, information and forms regarding proposal preparation are contained under Section III. Applicable RFP References.

The following specific RFP instructions and provisions apply to this Request For Proposal:

A. Proposal Intent Response Sheet (submit prior to proposal submission—by August 28, 1998)

B. Packaging and Delivery of Proposal

C. SIC Code and Small Business Size Standard

D. Number and Type of Award(s)

E. Estimate of Effort

F. Service of Protest

G. Technical Proposal Table of Contents

H. Page Limits

I. Other Provisions

A. PROPOSAL INTENT RESPONSE SHEET

RFP No. NHLBI-HV-98-24

TITLE OF RFP: Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE)

FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY **August 28, 1998**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

I INTEND TO SUBMIT A PROPOSAL

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
6701 ROCKLEDGE DR MSC 7924
BETHESDA MD 20892-7924

Attention: Dr. James Scheirer

or FAX TO: Dr. James Scheirer at (301) 480-3541

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:

"RFP NO. NHLBI-HV-98-24
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
PROTOCOL: ORIGINAL* AND Twenty-five (25) COPIES
MANUAL OF OPERATIONS: 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 Building, Room 7091
6701 ROCKLEDGE DR MSC 7924
BETHESDA MD 20892-7924

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

C. SIC CODE AND SMALL BUSINESS SIZE STANDARD

NOTE: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provisions entitled, SMALL BUSINESS PROGRAM REPRESENTATIONS, FAR 52.219-1:

The standard industrial classification (SIC) code for this acquisition is 8731.

The small business size standard is 500 employees.

THIS REQUIREMENT IS **NOT** SET-ASIDE FOR SMALL BUSINESS.

D. NUMBER AND TYPE OF AWARD(S)

It is anticipated that one award will be made as a fixed price contract to a Clinical Coordinating Network Center (CCNC). The CCNC will include a network of clinical units able to recruit a minimum of 500 patients.

The CCNC will pay the clinical units on a fixed-price per patient randomization and completed follow-up, upon successfully completing the tasks and required forms. Forms will be kept at minimum, and Atrial Natriuretic Peptide (ANP) levels are the only factor required by protocol that is not considered standard care. For details of the payment plan, see ARTICLE B.2. Prices.

E. Level of Effort. The Government considers that the personnel and estimated levels of effort listed below will be required for successful completion of the study. Effort is shown as a percentage of FTE (full time equivalent) labor. **The effort is listed below as information only and is not to be considered restrictive for proposal purposes.**

Labor Category	Yr 1	Yr 2	Pd 3 8 mo	Pd 4 10 mo
Principal Investigator	40%	20%	20%	20%
Sr. Biostatistician	50%	20%	20%	20%
Biostatistician	50%	50%	25%	25%
Administrator	50%	50%	50%	50%
Programmer	100%	50%	50%	50%
Data Entry	75%	100%	25%	10%
Secretary/Clerical	100%	80%	75%	50%
Total:	465%	370%	265%	225%

The Government considers that the personnel and estimated labor hours listed below will be required as subcontracted clinic or patient contact effort for successful completion of the study. Effort is shown as calculated cumulative hours of labor based on the projected clinic visit schedule of patients and omitting effort identified as normal care. **The effort is listed below as information only and is not to be considered restrictive for proposal purposes.**

Labor Category	Yr 1	Yr 2	Pd 3 8 mo	Total
Physician/Clinician	385.84	460.70	190.08	1,036.62
Nurse/Nurse Coordinator	1,260.73	1,492.99	605.65	3,359.37
Secretary/Clerical	1,134.71	1,375.49	547.29	3,057.49
Total:	2,781.28	3,329.18	1,343.02	7,453.48

F. SERVICE OF PROTEST

In accordance with FAR 52.233-2 SERVICE OF PROTEST (NOV 1988):

(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:

Ms. Sharon M. Kraft

Address:
National Institutes of Health
National Heart, Lung, and Blood Institute
Contracts Operations Branch
Rockledge 2, Room 6112
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

The copy of any protest shall be received in the office designated above within one day of filing a protest with GAO.

G. 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 RFP Number, Institution and Principal Investigator on the abstract.

4. **TECHNICAL PLAN** (no more than 50 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 located in the Streamlined RFP References under "FORMS, FORMATS, & ATTACHMENTS.")

7. **LITERATURE CITED** . . . . . Page #

8. **APPENDICES** . . . . . Page #

   Total number of appendices shall not exceed 100 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.

H. Page Limits

The offerors shall limit their responses to 150 pages. The technical approach must be limited to 50 pages. The other portions of the proposal, including related experience, personnel, etc., must be limited to 100 pages.

The cover sheet, abstract, table of contents, resources and facilities, other support, and literature cited are NOT "technical approach" and do not count against the 50 page limit. Consequently, the "technical approach" comprises item 4 of the "TECHNICAL PROPOSAL TABLE OF CONTENTS," exclusive of all subheadings except item a., Personnel. Note, however, that resumés or c.v.s or other documentation of individuals' capabilities should be provided in the appendices.

The **Protocol** and **Manual of Operations** shall be submitted separately as stand-alone documents along with the technical proposals. These are not to be counted within the page limitations set forth above.

I. OTHER PROVISIONS

1. GOVERNMENT FURNISHED FACILITIES AND EQUIPMENT—None.

2. POTENTIAL AWARD WITHOUT DISCUSSIONS—The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

3. COST/PRICING INFORMATION—The offeror's business proposal shall **not** include the basic cost/pricing information specified in the Standard RFP Instructions and Provisions, under the Streamlined RFP References Directory referenced in this RFP. However, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This

additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the Contracting Officer to evaluate the reasonableness of the price or to determine cost realism. The information may also include submission and certification of cost or pricing data.

A price computation spreadsheet has been constructed to assist offerors in understanding the Government's cost estimating assumptions. Also, if cost or pricing data should be determined later to be needed by the Contracting Officer, your pricing proposal may be required on a "just-in-time" basis on electronic media after determination of the competitive range. The spreadsheet is available at http://www.nhlbi.nih.gov/nhlbi/rafs/rfas.htm as a downloadable, self-executing zipped file, containing versions of the spreadsheet in Microsoft Excel, Lotus 1-2-3, and QuattroPro and an ASCII text instruction sheet, filename **readme.txt**. The name of the zipped file is **escaprop.exe**. Offerors are encouraged to download the zipped file and **expand** it

- by typing the filename followed by the enter key at a DOS prompt (or operating system prompt),
- **OR** using the Windows Explorer, right-clicking and selecting Open,
- **OR** browsing and inserting the filename into the "File, Run" or "Start, Run" blank for Windows 3.x or Windows95.

To view the spreadsheet, start one of these spreadsheet programs, select File, Open, and click on the "**escaprop.***" file that appears. The version with a filename suffix compatible with your software should be the only file appearing. The Readme.txt file should be accessible to most wordprocessor applications, to the DOS commands Edit [name of file] or Type [name of file] [> lpt1 for a printout], or by right-clicking in the Windows Explorer and selecting Open. The same file is available in PDF format as **readme.pdf**.

In case of legibility or file incompatibility problems, please e-mail the Contracting Officer at the address given in the cover notice with a full description of the problem and of the spreadsheet application software available to the user. We will endeavor to send a compatible version of the spreadsheet by return e-mail.

4. FAR 52.215-16, FACILITIES CAPITAL COST OF MONEY (October 1997) (This is applicable if you are a commercial organization and if a cost-reimbursement contract is awarded.)

5. Facilities capital cost of money (see FAR 15.408(h) will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

6. If the prospective Contractor does not propose this cost, the resulting contract (if cost-reimbursement) shall include the clause "Waiver of Facilities Capital Cost of Money."

7. PUBLICATION AND PUBLICITY (It is anticipated that this clause will appear in the contract.)

   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 acknowledgment substantially as follows:

   > This project has been funded in whole or in part with Federal funds from the National Institute of Dental Research, National Institutes of Health, under Contract No. . . .

8. HHSAR 352.270-6 PUBLICATION AND PUBLICITY (JULY 1991) (It is anticipated that this clause will appear in the contract.)

   > Unless otherwise specified in this contract, the Contractor is encouraged to publish, and make available through accepted channels, the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

III. APPLICABLE RFP REFERENCES

This section identifies the items located in the Streamlined RFP References that are applicable to this Request For Proposal (RFP).

A. The entire file entitled "STANDARD RFP INSTRUCTIONS AND PROVISIONS" is applicable to this RFP, except as modified by the inclusion of items from the "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS" below.

B. The following items are applicable from the file entitled "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS." The full text of the provisions is available in the file.

   List of provisions which apply to this specific RFP:

   E. Late Proposals, Modifications of Proposal, and

   M. Past Performance Information

   N. Facilities Capital Cost of Money

   O. "JUST IN TIME"

   Q. ADP Systems Security

C. The following items are applicable to this specific RFP and are located in the file entitled "FORMS, FORMATS, AND ATTACHMENTS," under Streamlined RFP References:

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities
3. Technical Proposal Cost Information

SUBMIT WITH BUSINESS PROPOSAL:

4. As the Business Proposal Cover Sheet, the Solicitation, Offer, and Award form SF-33, at the beginning of this document, specifically incorporating the Technical Proposal by reference.

5. Contract Pricing Proposal Cover Sheet, SF-1411, or equivalent, with every copy of business proposal.

6. Proposal Summary and Data record, NIH-2043, with every copy of business proposal.

7. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original. This form is not required if there are no lobbying activities to disclose.

8. Filled out and signed contract proposal including the cover sheet form SF-33 and all subsequent pages. This includes quantities, unit prices, and totals within Article B.2.

9. Representations and Certifications, only one completed and signed original. (Attached at end of this document.)

OTHER—TO BE SUBMITTED LATER:

10. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with Final Proposal Revision, if required by the Contracting Officer.

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

11. Invoice/Financing Requests Instructions for NIH Fixed Price Type Contracts, NIH(RC)-2

12. Procurement of Certain Equipment, NIH(RC)-7

The "SAMPLE CONTRACT FORMAT-GENERAL" under the Streamlined RFP References is **not** applicable to this RFP. The contract will include the clauses set forth in Sections A through K above (including L. IV. Project Information as set forth below).

IV. Project Information

Background and History

Recently, a concern has been raised about the benefits and safety of PAC. In response to these concerns, the NHLBI and the FDA co-sponsored a workshop in August 1997, entitled "Pulmonary Artery Catheterization and Clinical Outcomes (PACCO)." The purpose was to provide an objective assessment of the state-of-the science of PAC and its various uses. Experts in critical care, pulmonary medicine, cardiovascular medicine, surgery, pediatric cardiology, nursing, biostatistics, ethics, and medical economics identified several important clinical areas as priorities for clinical trials; persistent/refractory CHF (NYHA class IV) received top priority to test whether a PAC-directed treatment strategy achieves a better and less costly long-term outcome compared to a non-invasive treatment strategy. In addition to providing data on outcome, hospital utilization, and costs, the study would have additional benefits. For example, it would provide a clear benchmark for testing other technologies, now in developmental stages, that could supplant PAC in the future. At

this time careful evaluation of alternate technologies is impeded by a lack of comparative clinical data. Therefore, thorough evaluation of PAC in common clinical situations, such as CHF, would substantially advance the knowledge base of critical care medicine and would provide a firm foundation for testing of new device technology. Finally, the study would provide the basis for developing competency requirements for physicians, nurses, and others who insert and use pulmonary artery catheters, which was a strong recommendation of the PACCO Workshop.

Congestive Heart failure (CHF) constitutes one of the major categories of morbidity, particularly in elderly, and is responsible for utilization of significant resources, including a large number of hospitalizations (estimated at 800,000 to 2.3 million per year) and related health care costs. In 1993, 4.7 million Americans carried the diagnosis of CHF, and about 400,000 new cases are diagnosed every year. It is estimated that there are 800,000 to 1.2 million CHF patients with NYHA class III-IV symptoms. The diagnosis and treatment of CHF and its episodes of decompensation can be facilitated by pulmonary artery catheter (PAC) use, but its efficacy is highly dependent on the physician's experience in the treatment of such patients. Recently, concern has been raised about the benefits and safety of PAC, also known as Swan-Ganz catheterization.

I. Role of PAC in CHF

CHF patients have a high rate of cardiovascular events including sudden death. The potential uses of PAC for CHF at the bedside include:

(A) PAC can provide critical information on both establishing a proper diagnosis of heart failure and suggesting a course of therapy based upon objective evidence; and

(B) PAC can provide critical information in acute exacerbations of CHF, where the diagnosis has been established and therapy has been instituted, but the patient manifests episodes of decompensation leading to hospitalization.

The knowledge, experience, and judgment of the attending physician is critical in the choice of a noninvasive vs. an invasive procedure to make a diagnosis and select the optimal therapy, and the ability of individual physicians to assess the clinical situation noninvasively varies considerably.

The rationale for choosing PAC in this patient population is based on at least two hypotheses: (1) knowledge of pulmonary capillary wedge pressure (PCWP) and cardiac output and their responses to treatment will help to identify the most effective short-term regimen; and (2) selecting a drug intervention based on hemodynamic responses to the drug will sustain clinical improvement and reduce the need for rehospitalization. The first hypothesis is intuitively true and is supported by much anecdotal experience over the years. Titrating sodium nitroprusside, dobutamine, or diuretics to reduce PCWP and/or to increase cardiac output is an effective therapeutic strategy. The long-term benefit of this "tailored" approach to CHF management has been advocated. There is a concern, however, with this approach. This is based on evidence that (a) the symptoms of CHF and left ventricular function are not closely correlated, (b) there is a dissociation between improved hemodynamics with inotropic or certain vasodilator drugs and improved clinical end-points, such as exercise tolerance and life expectancy, and (c) experience has shown that some beta blocking drugs impair hemodynamics but improve outcomes. Other pharmacologic studies have shown concurrence between improved hemodynamics and clinical presentation. Documentation of improved outcomes from PAC-directed titration of drugs would provide important therapeutic information.

The second hypothesis has not been tested. If more precise correction of hemodynamic abnormality leads to better outcomes, then this management strategy might be widely used. At one time, certain vasodilator drugs, such as nitroglycerin and sodium nitroprusside, could only be administered in the invasive hemodynamic surveillance setting. However, that provision has been relaxed today. Nonetheless, titration of nitroglycerin or nitroprusside to an optimal level of PCWP can be a useful therapeutic strategy that may avoid hypotensive complications but whose benefit on long-term outcome has never been established. Bedside non-invasive assessment of stroke volume and cardiac output is now possible, allowing use of other agents, such as inotropes dobutamine and dopamine. However, the ability to titrate the drug to achieve a desired level of cardiac output cannot be accomplished in the absence of invasive monitoring. Whether this precision in drug administration in severe pump decompensation can improve outcomes has not been tested.

One population where PAC has been used frequently is those patients targeted for cardiac transplantation. In the United States, cardiac transplantation is performed in approximately 2,500 patients yearly and seriously considered in 10,000 to 15,000 patients. This number is small compared to the estimated 800,000 to 1.2 million patients with NYHA CHF class III-IV symptoms, and 100,000-200,000 whose severe symptoms persist despite routine initiation of therapy with angiotensin converting enzyme (ACE) inhibitors, diuretics, and digoxin. The experience with patients evaluated for transplantation may, however, provide insight also into strategies for other patients, such as those who are ineligible for transplantation. PAC is routinely employed in the evaluation of potential transplant candidates. However, the evidence supporting these approaches varies from very strong to non-existent. The current uses of PAC are as follows:

(1) to identify the degree and reversibility of pulmonary hypertension. Ample data show that pulmonary hypertension is a major factor contributing to early right heart failure after cardiac transplantation. The demonstration of "irreversible" pulmonary hypertension is a contra-indication for transplantation. This approach is based on strong evidence. In some cases hemodynamic measurements may be repeated after weeks or months in hope of later improvement on a chronic regimen. This may include "in-and-out or short stay" (24-48 hour) PAC use to lower pulmonary pressures, and periodic re-evaluation while awaiting transplantation. Routine direct re-evaluation of pulmonary pressures is a common practice in patients awaiting transplantation, and the risks and costs of PAC for this use are small compared to those associated with cardiac transplantation itself. However, there are no data documenting the benefits of such a strategy.

(2) After irreversible pulmonary hypertension is ruled out with PAC, PAC-based monitoring is often continued in potential transplant candidates to facilitate further adjustment of medical therapy. The data to support this practice is controversial. Such a strategy may allow transplantation to be deferred or avoided in ambulatory patients with severe symptoms considered previously "refractory," contributing unique prognostic information on expected survival with and without transplantation, while awaiting transplantation or for those in wait-and-see mode for patients not yet listed. There are no data to support such a PAC-directed approach. The common observation that clinical status of CHF often improves after referral to heart failure/transplant programs does not in itself validate the strategy of invasive monitoring.

Appreciation of the benefits of hemodynamic profiles derives to a large extent serendipitously from routine PAC use. PAC monitoring has been used in conjunction with successful restabilization of patients previously considered refractory to vasodilator and diuretic therapy. Cardiac output is often

increased with diuretics and vasodilators, without specific inotropic support. Most of the current oral regimens of vasodilators and diuretics remain effective over a period of months, when fluid balance is maintained. It is generally assumed that apparent diminution of clinical response to an initially effective vasodilator regimen results from fluid retention. On the other hand, interventions designed to specifically increase cardiac output with inotropic agents have had deleterious long-term effects.

The rationale for a PAC-directed approach is based on the assumptions that hemodynamic goals are relevant to clinical goals of improving symptoms and that achieving these goals may also improve survival without transplantation (or in some cases improve survival after transplant by improving pre-operative organ function and activity). Symptoms of resting dyspnea, particularly orthopnea, are associated with elevated left-sided filling pressures, and relief of resting dyspnea is associated with reduction of those pressures, although the transduction of pressure into symptoms varies widely between patients. A number of small and large experiences confirm the relationship between high cardiac filling pressures and mortality in CHF populations with markedly elevated mean filling pressures. These may be reflected in PCWP, right atrial pressure, the severity of mitral and tricuspid regurgitation, elevated ANP levels, and they may likely contribute to the development of right ventricular dysfunction, which is also a prognostic factor in this population. For potential transplant candidates, the contribution of cardiac output to prediction of outcome is much weaker and often absent.

It has not been possible to show, however, that hemodynamic information provides data beyond that available from careful clinical assessment, especially when that assessment is performed serially. Despite the plethora of sophisticated assays, simple clinical classification of NYHA class IV remains a powerful predictor of mortality. This is particularly true for a patient who remains in class IV after aggressive therapy to relieve resting symptoms.

B. Results Related To Selection Of Potential Endpoints

The following data come from further analysis of carefully conducted studies previously reported (1,2). They reflect the outcomes of patients who underwent PAC placement for evaluation of CHF and transplantation. For the purpose of this analysis, only patients with NYHA class IV symptoms, left ventricular ejection fraction $\leq$35%, and who are eligible for cardiac transplantation have been included. These data provide information on outcomes in the population of patients likely to be eligible for the PAC-strategy trial, as follows:

Mortality: Patients were censored at the time of transplantation if they were waiting at home until the procedure. Patients who deteriorated to require continuous hospitalization until the time of ("urgent") transplantation were estimated to have died without this support, with their last hospitalization before transplant considered an endpoint. It is assumed that other categories of patients, such as those with comorbidities, would have higher mortality. Six-month mortality in this group of patients was 24%. Due to the greater incidence of cardiomyopathy and early coronary artery disease in men, most populations of advanced CHF include 20-25% women. In this report, 22% were women, and the event rates were almost exactly the same in women and in men.

Hospitalization: Data collected from all hospitals for the 6 months prior to and after referral to a CHF center for PAC-guided therapy and subsequent systematic follow-up showed: (1) 6 months prior to referral: 2.0 hospitalizations/pt with a total of 429 hospitalizations, and (2) 6 months after referral: 0.29 hospitalizations/pt with a total of 63 hospitalizations. All patients were candidates for

transplantation. The prior and subsequent hospitalization rates would be expected to be higher in non-transplant candidates (3).

Mitral Regurgitation: At the time of admission a majority of patients have already been treated according to clinical assessment. Thus, most of the change in medical therapy between admission and discharge reflects the impact of PAC-guided therapy. Changes that can only be measured late, i.e., after the discharge, likely reflect the impact of other interventions incorporated in the CHF program. Several indices of mitral regurgitation are presented here. Mitral regurgitation area was measured as a fraction of atrial volume from color flow Doppler (4): prior to PAC the initial area was: 0.33 ± 0.16 cm, at hospital discharge: 0.13 ± 0.12 cm, and at 6 months: 0.09 ± 0.11 cm. Initial regurgitant fraction (using combined radionuclide and thermodilution techniques) decreased from 0.47 ± 0.44 to 0.15 ± 0.38 when PAC was removed. Recently published proximal isovelocity surface area mapping offers convenient serial measurements of the actual volume of regurgitant flow (6). Initial volume was reduced from 44 ± 33 cc to 12 ± 10 cc when PAC was removed. The reduction in mitral regurgitation during PAC-guided therapy has been consistent in several reports, though the number of patients studied is small.

Exercise: Level of exercise capacity is one of the important assessment factors and also a target of intervention. Peak myocardial consumption (V02) provides the most objective measurement. The largest change is observed in patients with the poorest initial exercise capacity, who are often not routinely studied at admission due to their obvious limitations. After PAC-based therapy, the peak V02 increased significantly by 3-6 months in the 70 of 174 patients in whom it was measured: from baseline 11 ± 3 ml/kg/min to 15 ± 4 ml/kg/min at 3-6 months. Exercise duration also increased from baseline 10 ± 4 minutes to 16 ± 4 minutes when PAC was removed (5). In a smaller study, the peak V02 increase was less marked and not significant after PAC-based therapy: from 12 ± 3 ml/kg/min at baseline to 14 ± 6 ml/kg/min at 6 months (8). In a more recent study, the exercise duration increased from baseline 9 ± 4 minutes to 13 ± 5 minutes at discharge (9).

Natriuretic Peptide Measurement: An additional index of physiologic and prognostic interest is the circulating level of natriuretic peptides (such as pro-ANP). This hormone family has been shown to reflect the elevation and changes in intracardiac filling pressures and to correlate with prognosis in both asymptomatic and severe CHF (10-12). However, it has not been measured systematically during PAC-guided therapy in severe CHF.

Statement of Work

The Study Design. It is anticipated that one award will be made as a fixed price contract to a Clinical Coordinating Network Center (CCNC). The CCNC will include a network of clinical units able to recruit a minimum of 500 patients.

The CCNC will pay the clinical units on a fixed-price per patient randomization and completed follow-up, upon successfully completing the tasks and required forms. Forms will be kept at minimum, and Atrial Natriuretic Peptide (ANP) levels are the only factor required by protocol that is not considered standard care. For details of the payment plan, see ARTICLE B.2. Prices.

Offerors will be expected to provide the final study protocol, including details of the study design, patient eligibility criteria, randomization procedure, analysis of the data, and manual of operations, based on the protocol considerations stipulated below.

A. Objective:

The major objective of the trial is:

To determine long-term safety and efficacy of PAC-directed treatment strategy compared to non-invasive treatment strategy in patients with severe CHF.

A secondary objective is:

To determine costs and resource utilization of PAC-directed treatment strategy compared to non-invasive treatment strategy in patients with severe CHF.

B. Sample size:

The offerors shall propose a two-arm trial, with 250 patients with class IV CHF to be randomized into each arm.

Compared to studies of milder CHF, the target population is likely to have more rehospitalizations for CHF. It is estimated that a total sample size of 500 patients will be needed for the two treatment strategies to ensure at least 80% power for a two-group comparison with $\alpha = 0.05$ to detect a benefit difference of 30% or greater in the primary endpoint. The estimated six-month event rate is 40% for the non PAC-directed therapy.

C. Eligibility Criteria:

Patients eligible for the trial must exhibit all of the following:

1) current hospitalization for CHF;

2) one previous hospitalization for CHF, during the past 6 months;

3) age > 16 years;

4) left ventricular ejection fraction $< 35\%$ for at least 3 months;

5) attempted therapy with ACEI and digoxin and/or diuretics in the past; and

6) NYHA class IV with clinical evidence of elevated filling pressures at rest e.g. (a) evidence of elevated intracardiac filling pressures: orthopnea, abdominal discomfort attributed to hepato-splenchnic congestion, peripheral edema, ascites, rales, and jugular venous distension to ≤ 5 cm above sternal angle; and (b) inadequate peripheral perfusion, i.e., cool extremities.

Exclusions:

1) acute CHF requiring PAC as a part of the management.

2) factors suggesting inability to comply with protocol.

D. Endpoints

1) The primary endpoint is combined endpoint of rehospitalization and death.

The protocol shall specify guidelines governing rehospitalization, as this is an outcome that could be influenced by the previous strategy of therapy. The requirement for two hospitalizations prior to PAC placement is to minimize the effect of crossover on endpoints. Crossovers from usual to PAC-guided therapy would be analyzed according to the intention-to-treat principle.

2) Other end-points of interest may include: echocardiographic documentation of LV function and mitral regurgitation, exercise stress test with V02 measurement, neurohormonal levels and natriuretic peptides.

The primary endpoint in this trial, which cannot be blinded, could be complemented by physiologic and functional secondary endpoints assessed in a blinded fashion. Both mitral regurgitation and exercise time have been shown to improve early during PAC-directed therapy and natriuretic peptides, with demonstrated prognostic importance, representing reasonable secondary endpoints to support the primary endpoint. These secondary endpoints could be measured at baseline, discharge, and three months.

E. Duration of the trial

The trial will consist of an Implementation, Recruitment , and Follow-up phase (32 months), and Analysis phase (10 months).

RANDOMIZED TREATMENT STRATEGIES

Patients will be randomized into the two treatment arms: 1) treatment strategy without PAC (Usual Group), and 2) treatment strategy guided by PAC (Hemodynamic Group). Data will be collected on these patients at entry, during the acute in-hospital period, and subsequently during follow-up. Collected data will include standard demographic data, pertinent information about the present illness, past medical history, recent medical treatment regimens within 6 months of the index hospitalization including all forms of hormonal replacement therapy (HRT), physical examination and protocol-required tests. At the time of discharge, a summary of selected vital signs, medications, physical activities, procedures, and major clinical events and complications will be entered on standardized forms. Following discharge from the hospital, a protocol-directed cardiovascular evaluation, health status assessment, and cost data will be collected at appropriate follow-up intervals.

Both arms will follow the same protocol, and the therapy will reflect standard clinical practice. The outline presented below may serve as guide for the protocol.

A. Clinical Arm Without Hemodynamic Monitoring (Usual Group)

In this group the therapy will be tailored to the following goals: a) absence of evidence of elevated intracardiac filling pressures: relief of orthopnea, relief of abdominal discomfort attributed to hepatosplenchnic congestion, resolution of peripheral edema, resolution of ascites, resolution of rales, and reduction of jugular venous distension to $\leq$ 5 cm above sternal angle; and b) adequate peripheral perfusion: warm extremities, if they can be achieved, and pulse pressure $\geq$25 %, or, if less, the greatest which can be achieved.

Either during or after hemodynamic monitoring, therapy may be further adjusted to achieve the clinical goals above and further adjusted, if necessary, to maintain adequate blood pressure and renal function for all patients. Regardless of whether or not the above goals have been achieved, all patients undergo adjustment of therapy to maintain the following on the discharge medical regimen:

1) freedom from symptoms of postural hypotension;

2) average systolic blood pressure $\geq$ 80 mmHg, lying and standing; and

3) serum creatinine $<$ 3.0 mg/dl and no more than 1.0 mg/dl above level at admission, and not increasing.

Patients for whom therapy is being adjusted without hemodynamic monitoring can crossover for hemodynamic monitoring at any time they reach certain criteria. The protocol should provide adequate information regarding specific drugs and dosages used. The criteria for cross-over could include any of the following:

1) need to add intravenous inotropic agents above 3 mcg/kg/min to prevent symptomatic hypotension;

2) repeated inability to discontinue low-dose inotropic agents; or

3) renal insufficiency defined as: urine output $<$ 300 cc in 12 hr or 800 cc/24 hr, or creatinine increase by at least 50% to over 2.5 mg/dl in the presence of jugular venous pressure $\geq$ 8 cm or uninterpretable.

B. PAC-Directed Hemodynamic Arm

In addition to the above clinical goals**,** therapy in this arm will be adjusted to achieve specific hemodynamic goals. For example, these goals could include the following:

1) PCWP $\leq$ 15 mmHg (18 will be acceptable when further efforts to decrease PCWP are not possible);

2) right atrial pressure $\leq$ 8 mmHg (unless Goal 1 is already met); and

3) maintenance of systolic blood pressure $\geq$ 80, except for occasional transient decreases to lower levels after oral medications.

One example of the approach to therapy includes the use of nitroprusside in patients with systemic vascular resistance $>$ 1300-1500. Nitroprusside when used would be started at 10 mcg/minute and titrated up by 10-40 mcg increments at 10-20 minute intervals. In most cases, other vasodilators will be discontinued during nitroprusside therapy, except nitrates in patients with known coronary artery disease. Diuretics are generally withheld during the first two to four hours of nitroprusside therapy except in patients with evident peripheral volume reservoirs or when the right atrial pressure is $>$ 15 mmHg, in whom they may be given any time after the first 30 minutes of nitroprusside. The general goal is to reach hemodynamic goals within 24 to 48 hours on nitroprusside, with maintenance of adequate hemodynamics for at least 8 to 12 hours before initiation of oral therapy and nitroprusside weaning and for at least 12 hours on oral therapy alone. The oral therapies used will be based on proven regimens, such as ACEI (captopril) with isosorbide dinitrates, and occasional substitution or supplementation with hydralazine when the goals achieved with nitroprusside cannot be maintained with captopril/isosorbide dinitrate. Other therapies recently proven to be safe and efficacious should also be considered.

Either during or after hemodynamic monitoring, therapy may be further adjusted to achieve the clinical goals above and further adjusted, if necessary, to maintain adequate blood pressure and renal function for all patients. Regardless of whether or not the above goals have been achieved, all patients undergo adjustment of therapy to maintain the following on the discharge medical regimen.

MEDICAL THERAPY FOR ALL PATIENTS

For all patients randomized, therapy will be tailored to the ultimate goal of discharge on an oral medical regimen to provide better relief of CHF symptoms, to reduce filling pressures, and to maintain adequate perfusion. These goals are the same for both groups, but in the usual therapy arm,

therapy will be adjusted according to clinical assessment alone, while in the PAC-directed arm, actual measurement of hemodynamics will be used to supplement clinical assessment.

The oral medical regimen for discharge would be based on the standard available medications, such as angiotensin converting enzyme inhibitors (ACEI), nitrates, hydralazine, furosemide and other diuretic agents. Intravenous diuretics could be used when major diuresis is desired, with subsequent change to oral diuretics at least 48 hours before discharge. If necessary, physicians may, but would not be encouraged to, use low dose infusions of dopamine or dobutamine (at ≃ 3 micrograms/kg/min) to facilitate diuresis or other changes in the medical regimen. Intravenous nitroprusside may be used in either group, monitored by automatic blood pressure in the usual group and by likely invasive measures in the PAC group.

OTHER PROTOCOL CONSIDERATIONS

A. Eligibility for Discharge--All Patients

Regardless of the goals by which therapy was adjusted while in hospital, the following conditions would need to be met prior to discharge:

1) 24 hours on oral medications alone without major medication change (except anticoagulation); and 48 hours after discontinuation of any intravenous inotropic medications;

2) **stable fluid balance (optimal or stable weight)**;

3) patient education; and

4) disposition (home services and follow-up appointment).

B. Post-Discharge Management

Further management will be the same for both groups, according to standard practice. It is anticipated that patients will be followed for adjustment of CHF medications in their heart failure clinics at regular intervals, such as 1-2 weeks, 4 weeks, 3 months, and 6 months and more often if clinically indicated. All information regarding the hospitalization and subsequent clinic visits will be communicated to the other physicians involved in the patient's care.

RECRUITMENT

Active recruitment for the trial will last 27 months. All participants will be recruited in the hospital while being evaluated for recurrent episode of CHF.

A. Cost related to the research care:

This cost will include patient screening and recruitment, patient follow-up for 6 months, data collection (as specified below), and analysis, and publication activities. The research cost will include cost of tests, such as natriuretic peptide characterization, not considered as a part of the routine care and therefore, not reimbursed by third party coverage.

B. Cost related to standard care:

As the study objective is to test the role of PAC in the management of patients with severe CHF, the randomization provides for not performing PAC in the half of patients who might otherwise have it. Therefore, it is anticipated that the care specified in the protocol will be related to standard care and not reimbursed by the contract funds.

ROUTINE DATA COLLECTION

1. Blood pressure, weight at each visit, collected as part of standard care.
2. ECG at pre-randomization visit and at each hospitalization, collected as part of routine clinical care.
3. Serum electrolytes, CBC, and other blood work, collected as part of routine clinical care.
4. Echocardiogram at the randomization visit and 6 month follow-up, collected as part of routine clinical care. Echocardiogram at the time of discharge from the index hospitalization, collected as part of the protocol-directed care.
5. Exercise stress test with V02 measurements during index hospitalization and 6 month follow-up, collected as part of routine clinical care.

6 Natriuretic hormone profile at the randomization visit, discharge, and 6 month follow-up, collected as part of protocol-directed care.

7. Assessment of relevant medical history, including end points, side effects, hospitalizations, and quality of life at appropriate intervals.
8. Compliance with the protocol requirements.

ECHOCARDIOGRAPHIC DATA

The offeror may provide for Central Echocardiographic interpretation of echocardiographic data collected on all participants during the study. In relation to the performance of the measurements, the offeror will specify standardized methods for proper performance at the clinical units, collection, and analysis in a manner that assures validity of results.

FOLLOW-UP ACTIVITIES

Table 1 Evaluations	**Schedule of Evaluations—weeks after randomization**					
	Rand	**Disch**	**2-4**	**8**	**12**	**24**
History & Exam	X	X	X	X	X	X
Exercise Stress Test	**opt**	**X**				**opt**
Events Check		X	X	X	X	X
ECG	X	X			X	X
Echocardiogram	X	**opt**				X
Neuropeptides	X	X				X
Drug Effects Check	X	X	X	X	X	X
Quality of Life	X	X	X		X	X
Costs (Option)		X				X

Opt = optional (selected by the offeror)

ORGANIZATIONAL STRUCTURE

The anticipated organizational structure and responsibilities of the ESCAPE trial follow those of similar NHLBI trials. The main component will be a Steering Committee consisting of representatives from Clinical Coordinating Network Center (CCNC) including scientific leaders from the CCNC network, Central Echocardiographic unit (if present), and data coordinating staff.

A. Steering Committee: Scientific leadership will be provided by the Steering Committee. The members of the Steering Committee will be representatives from major medical sites within the Clinical Coordinating Network Center, Study Chair, and the NHLBI. All substudy and/or ancillary study requests will be reviewed by the Operation Committee for scientific merit and approved or disapproved by the Steering Committee. It is anticipated that the Steering Committee will meet at least annually.

Day-to-day trial operations will be run by the Operations Committee as an extension of the Steering Committee, with the representatives from the CCNC, Study Chair, NHLBI, and other participants as required to ensure efficient, high quality performance. It is anticipated there will be weekly conference calls during the recruitment phase of the study, biweekly thereafter. These calls will be conducted to ensure that important issues are appropriately addressed and problems solved. Protocol changes will be discussed by the Operation Committee and will be ratified by the Steering Committee.

B. Study Chairperson: The ESCAPE trial will have a Study Chairperson appointed by the NHLBI Director. The Study Chair will have leadership responsibility for the scientific direction of the trial. The Study Chair will: advise the NHLBI on data monitoring and other issues of importance to the overall trial; maintain, with advice from other study participants, an internal organizational structure that meets the needs of the trial and the NHLBI; be informed about all aspects of study operations; assist with formulation of the study policy; take action as necessary to ensure smooth and efficient operation of the trial; and appoint study participants to appropriate positions and committees as needed.

C. Clinical Coordinating Network Center (CCNC): It is anticipated that the CCNC will consist of a network of collaborating clinical units. The unit may consist of medical site(s) or clinicians that will be involved in the evaluation, enrollment, follow-up, and treatment of patients in the trial. The CCNC will be responsible for recruitment of 500 patients, protocol implementation within their network, and clinical care quality assurance according to the trial protocol. During the Recruitment Phase, the CCNC will implement activities related to initiation and monitoring of recruitment activities within the network. In the case of recruitment problems, the CCNC will have the primary responsibility for evaluating and correcting the problems, including certification of a new site(s) and IRB clearances and assurances, termination of recruitment at existing sites, and appropriate follow up of patients enrolled from terminated site. Such decisions will be made with approval of the Project Officer.

Throughout the course of the study, the CCNC will assume responsibility for implementation of and compliance with the protocol, including standardization and quality control procedures and data coordinating activities within the network, including individual clinical sites and Core Laboratory, and assure timely data collection and analysis. During the recruitment phase the CCNC will keep a log of all screened patients (excluding names) along with reasons for exclusion from randomization.

It will also coordinate study activities within the network and facilitate communications among all organizational study components. This may include meetings of study committees and appropriate subcommittees. The CCNC will prepare and distribute regular progress reports and minutes, prepare and distribute reports and minutes for the DSMB, assure the quality and accuracy of data collection, and monitor endpoint results.

It is possible that the study protocol may call for serial echocardiographic data to be collected and interpreted centrally. In such case, the CCNC will be responsible for establishment of central interpretation, including specific protocol development and distribution, timely data gathering and analysis, and incorporation of such data into the CCNC database for further analysis.

D. Morbidity and Mortality Classification Committee: A Morbidity and Mortality Classification Committee (MMCC) will establish guidelines for coding causes of death, diagnosis of MI, and evaluation of other cardiac events. These guidelines will be provided to the Steering Committee. The MMCC will regularly review and adjudicate suspected trial endpoints, both fatal and nonfatal cardiac events, while blinded for group assignment. It is anticipated that most of the activities will not require regular meetings.

E. Data and Safety Monitoring Board: An independent Data and Safety Monitoring Board (DSMB) will be appointed by the NHLBI. Members will be senior experts in the area of cardiovascular medicine, biostatistics, and bioethics. The Study Chair, the Director of the CCNC, and representatives from the NHLBI will also participate as non-voting members. Interim and final results will be submitted to the DSMB. The DSMB will review the data approximately twice a year to monitor safety and to advise the Institute about study progress. It is anticipated that the DSMB will meet at least once a year, with options for a conference call reviews as needed. In addition, the CCNC will provide data to the DSMB Chair at regular intervals to ensure early identification of any major adverse outcomes of therapy. The DSMB will review any changes in the protocol recommended by the Steering Committee. The DSMB will formulate recommendations for continuation or termination of the trial based on evidence of beneficial or adverse effects of therapy or on the ability to enroll patients. Recommendations by the DSMB must be approved by the NHLBI prior to implementation.

Phasing

The ESCAPE study shall be conducted in two phases: Phase I--Implementation, Recruitment and Follow-up (Recruitment shall not be started until receipt of authorization by Contracting Officer) and Phase II--Close Out and Analyses. The proposed time-table is as follows:

Phase I--Implementation, Recruitment, and Follow-up (32 months)

1. Implement the study protocol.
2. Distribute manual of operations within the CCNC network units.
3. Activate communication and data gathering links within the CCNC network units.
4. Standardize data collection from the clinical units and test forms for recording data.
5. Assume responsibility for regular communication between representatives of the CCNC, and the Program and Contract Offices.

6. Randomly assign a total of 500 patients into the ESCAPE trial over 27 months, with 250 patients randomly assigned to the clinical arm without hemodynamic monitoring (usual group) and 250 patients randomly assigned to the PAC (hemodynamic arm).
7. Assume the primary responsibility for evaluating and correcting problems, including certification of new clinical units, termination of recruitment at existing sites, and appropriate follow up of patients enrolled from the terminated site. It is anticipated that site visits to clinical units will be necessary to assure recruitment and monitor the quality of data.
8. Provide weekly recruitment reports to all enrolling sites and the Project and Contract Offices accessible by the Web/internet.
9. Assume the primary responsibility for patient follow-up.
10. Conduct weekly or biweekly conference calls of the Operations Committee regarding study progress.
11. Collect and enter into the database all clinical information and test data required by the protocol in a timely fashion, and have the format internet ready.
12. Accumulate and maintain appropriate data files on all patients in a timely manner, including data entry and editing.
13. Maintain confidentiality and security of data files.
14. Review on a regular basis and assure the high quality of all data obtained.
15. Assume the primary responsibility for monitoring major adverse effects and patient compliance during the study. Assume the primary responsibility for reporting major and life threatening events to the Program Office within 48 hours of being informed of the event.
16. Assume the responsibility for correcting problems related to missed, delayed, and erroneous data.
17. Establish, organize, and conduct reviews of the Morbidity and Mortality Classification Committee (MMCC) to classify all major adverse events in uniform fashion. The MMCC will report the results to the data coordinating facility.
18. Prepare and distribute monthly reports on data quality and clinical performance (enrollment, protocol compliance, form completion) within the CCNC network units and to the Program Office, and have the report internet format ready.
19. Assume responsibility for regular communication between representatives of the CCNC and the Program Office.
20. Record, produce, and distribute Steering Committee, MMCC, and other relevant meeting minutes.
21. Regularly prepare a report of patient screening, recruitment, status of data collection and quality control, or any other matters needed to be discussed at Steering Committee meetings and as needed.
22. Begin analyses of all data in preparation of manuscripts for publication.

23. Assume responsibility for arranging and conducting regular DSMB activities (anticipated semiannual communications, i.e., conference calls and annual meetings for approximately 4 members of the DSMB).

Phase II--Close Out and Analyses (10 months)

The contractor shall:

1. Finalize and verify all data collection.
2. Complete analysis of all study data.
3. Assume the primary responsibility for preparation of reports and scientific manuscripts in collaboration with the NHLBI staff.
4. Assume the primary responsibility for dissemination of the results of the study.
5. Provide a final report which documents and summarizes the results of the entire contract work, including recommendations and conclusions based on the experience and results obtained. The final report shall include tables, graphs, diagrams, curves, sketches, photographs, and drawings in sufficient detail to explain comprehensively the results achieved under the contract.

Data, data rights, patents, copyrights. The contract will involve the use of human subjects; therefore, the Privacy Act will be included in the contract to prohibit release of individually identifiable information to the Government or any third party. Information on individually identifiable subjects will not be used in any reports or analyses. It is anticipated that patient or copyright questions will not arise from this study, which is designed to measure the effectiveness of existing, accepted therapies.

Replication, dissemination, or use of the results. The data obtained in this study have the potential to increase the understanding of PAC directed therapy and may provide a rationale for safe and effective treatment of patients with CHF, and ultimately may provide for a more favorable prognosis. It is anticipated that this information will be disseminated via publication in scientific literature and presentation at national meetings. The contract will include the NHLBI Public Use Data clauses.

Post-Award Administration and Monitoring. The progress of this program will be monitored by the Project Officer, Contracting Officer, and outside consultants when necessary. Routine technical progress reports and financial reports or invoices are anticipated to be the primary means of monitoring performance. However, site visits and/or reverse site visits may be needed.

SECTION M—EVALUATION FACTORS FOR AWARD WITH TECHNICAL EVALUATION CRITERIA

GENERAL

Proposals submitted in response to this RFP will be reviewed by (1) a primary technical review group using peer review procedures under the auspices of Review Branch, DEA and (2) a secondary review group composed primarily of members of the DHVD, NHLBI professional staff.

Technical factors will be paramount in the decision to award a contract. The basis of evaluation includes the base award period and all option periods.

Although technical factors are paramount in the decision to award a contract, price will be evaluated and is a substantial factor in the source selection decision. If two or more offerors are approximately equal in technical ability, then price may become paramount. In any event, the Government reserves the right to make an award to the best advantage of the Government, price and other factors considered.

This research project involves human subjects. NIH Policy requires that women, members of minority groups and their subpopulations, and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and children are not feasible, a detailed rationale and justification for exclusion from the study population must be submitted with the technical proposal. The NHLBI will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities, and children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

The primary atherosclerotic based CHF is very rare in children under age 16, as compared to "children" over 16 and adults, and extraordinary effort would be needed to include children. The issues of study design and results would preclude direct applicability of intervention to children under age 16. Therefore, a separate age specific study in children would be preferable and warranted.

Offerors that do not propose a specific protocol and manual of operations will not be considered for award. Award of a contract under this RFP will be made only to offerors located in the U.S. Proposals from offerors outside the U.S. will not be considered for award.

The factors to be evaluated are as follows:

No.	**Criterion**	**Points**
1.	Adequacy of documentation showing an ability to recruit a total of 500 patients, including: **!** prior experience in multicenter clinical trials in cardiovascular disease **!** ability to implement study protocol, in a standardized fashion **!** ability to coordinate a follow-up of study patients	**50**
2.	Adequacy of the study protocol and manual of operations to meet the requirements of the Statement of Work.	**20**
3.	The specific competence of professional, technical, and administrative staff, pertinent to the operation of the CCNC, collaborating in multicenter clinical trials in cardiovascular disease, on site medical consultation, and the time these professionals will devote to the project, and the organizational and administrative structure of the proposed CCNC.	**20**
4.	Adequacy of the institutional commitment to the program, and of the proposed facility, technical hardware, and space.	**10**
	Total:	**100**

PART IV - SECTION K

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

1.	FAR 52.203-2	Certification of Independent Price Determination
2.	FAR 52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (DEVIATION)
3.	FAR 52.204-3	Taxpayer Identification
4.	FAR 52.204-5	Women-Owned Business
5.	FAR 52.204-6	Data Universal Numbering System (DUNS) Number
6.	FAR 52.209-5	Certification Regarding Debarment, Suspension, Proposed Debarment and Other Responsibility Matters
7.	FAR 52.215-4	Type of Business Organization
8.	FAR 52.215-6	Place of Performance
9.	FAR 52.219-1	Small Business Program Representations
10.	FAR 52.219-19	Small Business Concern Representation for the Small Business Competitiveness Demonstration Program
11.	FAR 52.219-21	Small Business Size Representation for Targeted Industry Categories Under the Small Business Competitiveness Demonstration Program
12.	FAR 52.222-21	Certification of Nonsegregated Facilities
13.	FAR 52.222-22	Previous Contracts and Compliance Reports
14.	FAR 52.222-25	Affirmative Action Compliance
15.	FAR 52.222-48	Exemption From Application of Service Contract Act Provisions
16.	FAR 52.223-1	Clean Air and Water Certification
17.	FAR 52.223-4	Recovered Material Certification
18.	FAR 52.223-13	Certification of Toxic Chemical Release Reporting
19.	FAR 52.225-1	Buy American Certification
20.	FAR 52.225-6	Balance of Payments Program Certificate
21.	FAR 52.225-8	Trade Agreements Act Certificate (DEVIATION)
22.	FAR 52.225-20	Buy American Act - North American Free Trade Agreement Implementation Act - Balance of Payments Program Certificate
23.	FAR 52.226-2	Historically Black College or University and Minority Institution Representation
24.	FAR 52.227-6	Royalty Information
25.	FAR 52.230-1	Cost Accounting Standards Notices and Certification
26.	-----	Certification Regarding Environmental Tobacco Smoke
27.	-----	Certification of Institutional Policy on Conflict of Financial Interest
28.	FAR 15.406-2	Certificate of Current Cost or Pricing Data

To Be Completed by the Offeror: **(The Representations and Certifications must be executed by an individual authorized to bind the offeror.)** The offeror makes the following Representations and Certifications as part of its proposal **(check/complete all appropriate boxes or blanks on the following pages)**.

(Name of Offeror)	**(RFP No.)**
(Signature of Authorized Individual)	**(Date)**
(Typed Name of Authorized Individual)	

Note: The penalty for making false statements in offers is prescribed in 18 U.S.C 1001.

1. **52.203-2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APRIL 1985)**

(a) The offeror certifies that -

(1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered;

(2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and

(3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory--

(1) Is the person in the offeror's organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above; or

(2) (i) Has been authorized in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above

.....
.....
[insert full name of person(s) in the offeror's organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror's organization];

(ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and

(iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above.

(c) If the offeror deletes or modifies subparagraph (a)(2) above, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

2. **52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (DEVIATION)**

(a) The definitions and prohibitions contained in the clause, at FAR 52.203-12, Limitations on Payments to Influence Certain Federal Transactions, included in this solicitation, are hereby incorporated by reference in paragraph (b) of this certification.

(b) The offeror, by signing its offer, hereby certifies to the best of his or her knowledge and belief that on or after December 23, 1989 -

(1) No Federal appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of a contract resulting from this solicitation.

(2) If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with this solicitation, the offeror shall complete and submit with its offer, OMB Standard Form-LLL, "Disclosure of Lobbying Activities", to the Contracting Officer, and

(3) He or she will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of $100,000 shall certify and disclose accordingly.

(c) Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by section 1352, Title 31, United States Code. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure form to be filed or amended by this provision, shall be subject to a civil penalty of not less than $10,000, and not more than $100,000, for each such failure.

3. **52.204-3 TAXPAYER IDENTIFICATION (JUNE 1997)**

(a) Definitions.

"Common Parent," as used in this solicitation provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

"Corporate status," as used in this solicitation provision, means a designation as to whether the offeror is a corporate entity, an unincorporated entity (e.g., sole proprietorship or partnership), or a corporation providing medical and health care services.

"Taxpayer Identification Number (TIN)," as used in this solicitation provision, means the number required by the IRS to be used by the offeror in reporting income tax and other returns.

(b) All offerors are required to submit the information required in paragraphs (c) through (e) of this solicitation provision in order to comply with reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M and implementing regulations issued by the Internal Revenue Service (IRS). If the resulting contract is subject to the reporting requirements described in FAR 4.903, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

(c) Taxpayer Identification Number (TIN).

( ) TIN:_____
( ) TIN has been applied for.
( ) TIN is not required because:
  ( ) Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the U.S. and does not have an office or place of business or a fiscal paying agent in the U.S.;
  ( ) Offeror is an agency or instrumentality of a foreign government;
  ( ) Offeror is an agency or instrumentality of a Federal, state or local government;
  ( ) Other, State basis _____

(d) Corporate Status.

( ) Corporation providing medical and health care services, or engaged in the billing and collecting of payments for such services;
( ) Other corporate entity;
( ) Not a corporate entity:
  ( ) Sole proprietorship
  ( ) Partnership
  ( ) Hospital or extended care facility described in 26 CFR 501(c)(3) that is exempt from taxation under 26 CFR 501(a).

(e) Common Parent.

( ) Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.
( ) Name and TIN of common parent:

Name _____
TIN _____

4. **52.204-5 WOMEN-OWNED BUSINESS (OCTOBER 1995)**

(NOTE: If this requirement is set-aside for Small Business Concerns, it is not necessary to complete this certification.)

(a) **Representation**. The offeror represents that it **[ ]** is, **[ ]** is not a women-owned business concern.

(b) **Definition**. "**Women-owned business concern**," as used in this provision, means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

5. **52.204-6 DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER (APRIL 1998)**

(a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" followed by the DUNS number that identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services.

(b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one. A DUNS number will be provided immediately by telephone at no charge to the offeror. For information on obtaining a DUNS number, if located within the United States, the offeror should call Dun and Bradstreet at 1-800-333-0505. The offeror should be prepared to provide the following information:

(1) Company name.
(2) Company address.
(3) Company telephone number.
(4) Line of business.
(5) Chief executive officer/key manager.
(6) Date the company was started.
(7) Number of people employed by the company.
(8) Company affiliation.

(c) Offerors located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet home page at http://www.dnb.com/. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at globalinfo@mail.dnb.com.

6. **52.209-5 CERTIFICATION REGARDING DEBARMENT, SUSPENSION, PROPOSED SUSPENSION, PROPOSED DEBARMENT AND OTHER RESPONSIBILITY MATTERS (MARCH 1996)**

(NOTE: Applies to contracts expected to exceed $100,000.)

(a) (1) The Offeror certifies, to the best of its knowledge and belief, that -

(i) The Offeror and/or any of its Principals --

(A) Are **[ ]**, are not **[ ]** presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have **[ ]**, have not **[ ]**, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are **[ ]**, are not **[ ]** presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in subdivision (a)(1)(i)(B) of this provision.

(ii) The Offeror has **[ ]**, has not **[ ]**, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principals" for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager, plant manager, head of a subsidiary, division, or business segment, and similar positions).

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER SECTION 1001, TITLE 18, UNITED STATES CODE.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making an award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

7. **52.215-4 TYPE OF BUSINESS ORGANIZATION (OCTOBER 1997)**

The offeror or respondent, by checking the applicable box, represents that -

(a) It operates as **[ ]** an individual, **[ ]** a partnership, **[ ]** a nonprofit organization, **[ ]** a joint venture, or **[ ]** a corporation incorporated under the laws of the State of _____.

(b) If the offeror or respondent is a foreign entity, it operates as **[ ]** an individual, **[ ]** a partnership, **[ ]** a nonprofit organization, **[ ]** a joint venture, or **[ ]** a corporation, registered for business in _____.
country

8. **52.215-6 PLACE OF PERFORMANCE (OCTOBER 1997)**

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, **[ ]** intends, **[ ]** does not intend **(check applicable block)** to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance (Street Address (City, State, County, Zip Code)	**Name and Address of Owner and Operator of the Plant or Facility if Other than Offeror or Respondent**

9. **52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (FEBRUARY 1998)**

(Note: This provision applies to solicitations exceeding the micro-purchase threshold when the contract is to be performed in the United States, its territories or possessions, Puerto Rico, the Trust Territory of the Pacific Islands, or the District of Columbia.)

(a) (1) The standard industrial classification (SIC) code for this acquisition is [INSERT SIC CODE].

(2) The small business size standard is [INSERT SIZE STANDARD].

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) **Representations**.

(1) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a small business concern.

(2) (**Complete only if offeror represented itself as a small business concern in paragraph (b)(1) of this provision**.) The offeror represents as part of its offer that **[ ]** it is, **[ ]** is not a small disadvantaged business concern.

(3) (**Complete only if offeror represented itself as a small business concern in paragraph (b)(1) of this provision**.) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a women-owned small business concern.

(c) **Definitions**.

Joint venture, for purposes of a small disadvantaged business (SDB) set-aside or price evaluation preference (as prescribed at 13 CFR 124.321), is a concern that is owned and controlled by one or more socially and economically disadvantaged individuals entering into a joint venture agreement with one or more business concerns and is considered to be affiliated for size purposes with such other concern(s). The combined annual receipts or employees of the concerns entering into the joint venture must meet the applicable size standard corresponding to the SIC code designated for the contract. The majority of the venture's earnings must accrue directly to the socially and economically disadvantaged individuals in the SDB concern(s) in the joint venture. The percentage of the ownership involvement in a joint venture by disadvantaged individuals must be at least 51 percent.

Small business concern, as used in this provision, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Small disadvantaged business concern, as used in this provision, means a small business concern that (1) is at least 51 percent unconditionally owned by one or more individuals who are both socially and economically disadvantaged, or a publicly owned business having at least 51 percent of its stock unconditionally owned by one or more socially and economically disadvantaged individuals, and (2) has its management and daily business controlled by one or more such individuals. This term also means a small business concern that is at least 51 percent unconditionally owned by an economically disadvantaged Indian tribe or Native Hawaiian Organization, or a publicly owned business having at least 51 percent of its stock unconditionally owned by one or more of these entities, which has its management and daily business controlled by members of an economically disadvantaged Indian tribe or Native Hawaiian Organization, and which meets the requirements of 13 CFR Part 124.

Women-owned small business concern, as used in this provision, means a small business concern-

(1) Which is at least 51 percent owned by one or more women or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(d) **Notice**.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small or small disadvantaged business concern in order to obtain a contract to be awarded under the preference programs established pursuant to sections 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall-

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

10. **52.219-19 SMALL BUSINESS CONCERN REPRESENTATION FOR THE SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM (JANUARY 1997)**

(This representation must be completed if the acquisition is for one of the four designated industry groups of the Small Business Competitiveness Demonstration Program [includes Construction Contracts under SIC codes that comprise major groups 15, 16 and 17 [excluding dredging - Federal Procurement Data System [FPDS] service codes Y216 and Z216], refuse systems and related services (including trash/garbage collection services but excluding those for hazardous waste), contracts under SIC Code 4212 or 4953, limited to FPDS service code S205], architectural and engineering services [including surveying and mapping] contracts under SIC code 7389, 8711, 8712, or 8713, which are awarded under FAR Subpart 36.6 [limited to FPDS service codes C111 through C216, C219, T002, T004, T008, T009, T014, and R404), non-nuclear ship repair [not applicable to HHS]).

(a) **Definition**

"Emerging small business" as used in this solicitation, means a small business concern whose size is no greater than 50 percent of the numerical size standard applicable to the standard industrial classification code assigned to a contracting opportunity.

(b) **(Complete only if offeror has represented itself under the provision at FAR 52.219-1 as a small business concern under the size standards of this solicitation.)**

The Offeror **[ ]** is, **[ ]** is not an emerging small business.

(c) **(Complete only if the Offeror is a small business or an emerging small business, indicating its size range.)**

Offeror's number of employees for the past twelve months **(check this column if size standard stated in solicitation is expressed in terms of number of employees)** or Offeror's average annual gross revenue for the last 3 fiscal years **(Check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)**

Number of Employees	**Average Annual Gross Revenues**
[ ] 50 or fewer	[ ] $1 million or less
[ ] 51 - 100	[ ] $1,000,001 - $2 million
[ ] 101 - 250	[ ] $2,000,001 - $3.5 million
[ ] 251 - 500	[ ] $3,500,001 - $5 million
[ ] 501 - 750	[ ] $5,000,001 - $10 million
[ ] 751 - 1,000	[ ] $10,000,001 - $17 million
[ ] Over 1,000	[ ] Over $17 million

11. **52.219-21 SMALL BUSINESS SIZE REPRESENTATION FOR TARGETED INDUSTRY CATEGORIES UNDER THE SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM (JANUARY 1997)**

(Complete only if the Offeror has represented itself under the provision 52.219-1 as a small business concern under the size standards of this solicitation.)

(NOTE: This representation must be completed if this solicitation covers one of the ten targeted industry categories under the Small Business Competitiveness Demonstration Program and if the offeror has certified itself under the clause at FAR 52.219-1 to be a small business concern under the size standards of this solicitation).

Offeror represents as follows:

Offeror's number of employees for the past twelve months **(check this column if size standard stated in solicitation is expressed in terms of number of employees)** or Offeror's average annual gross revenue for the last three fiscal years **(check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)**

No. of Employees	**Average Annual Gross Revenues**
[ ] 50 or fewer	[ ] $1 million or less
[ ] 51 - 100	[ ] $1,000,001 - $2 million
[ ] 101 -250	[ ] $2,000,001 - $3.5 million
[ ] 251 - 500	[ ] $3,500,001 - $5 million
[ ] 501 - 750	[ ] $5,000,001 - $10 million
[ ] 751 - 1,000	[ ] $10,000,001 - $17 million
[ ] Over 1,000	[ ] Over $17 million

The ten targeted industries are as follows:

Product Service Code	SIC Code	Description
G004	8742	Counseling/Training/Social Rehabilitation Services
J099	7699	Maintenance, Repair and Rebuilding of Equipment (Office Machines, Text Processing Systems & Visible Record Equipment)
K099	7699	Modification of Equipment (misc.)
Q210	8099, 8742	General Health Care Services
R406	8742	Policy Review/Development Services
R497	7299	Personal Services
6505	2833, 2834 2835, 2836	Drugs and Biologics
7045	3572, 3695 5065	ADP Supplies
7110	5021	Office Furniture
7510	5112	Office Supplies

12. **52.222-21 CERTIFICATION OF NONSEGREGATED FACILITIES (APRIL 1984)**

(a) "Segregated facilities," as used in this provision, means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees, that are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin because of habit, local custom or otherwise.

(b) By the submission of this offer, the offeror certifies that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. The offeror agrees that a breach of this certification is a violation of the Equal Opportunity clause in the contract.

(c) The offeror further agrees that (except where it has obtained identical certifications from proposed subcontractors for specific time periods) it will-

(1) Obtain identical certifications from proposed subcontractors before the award of subcontracts under which the subcontractor will be subject to the Equal Opportunity clause;

(2) Retain the certification in the files ; and

(3) Forward the following notice to the proposed subcontractors (except if the proposed subcontractors have submitted identical certifications for specific time periods):

NOTICE TO PROSPECTIVE SUBCONTRACTORS OF REQUIREMENT FOR CERTIFICATIONS OF NONSEGREGATED FACILITIES

A Certification of Nonsegregated Facilities must be submitted before the award of a subcontract under which the subcontractor will be subject to the Equal Opportunity Clause. The certification may be submitted for all subcontracts during a period (i.e. quarterly, semiannually, or annually).

NOTE: The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

13. **52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (APRIL 1984)**

The offeror represents that --

(a) It **[ ]** has, **[ ]** has not participated in a previous contract or subcontract subject either to the Equal Opportunity clause of this solicitation, the clause originally contained in Section 310 of Executive Order No. 10925, or the clause contained in Section 201 of Executive Order No. 11114;

(b) It **[ ]** has, **[ ]** has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

14. **52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APRIL 1984)**

The offeror represents that (a) it **[ ]** has developed and has on file, **[ ]** has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it **[ ]** has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

15. **52.222-48 EXEMPTION FROM APPLICATION OF SERVICE CONTRACT ACT PROVISIONS FOR CONTRACTS FOR MAINTENANCE, CALIBRATION, AND/OR REPAIR OF CERTAIN INFORMATION TECHNOLOGY, SCIENTIFIC AND MEDICAL AND/OR OFFICE AND BUSINESS EQUIPMENT--CONTRACTOR CERTIFICATION (AUGUST 1996)**

(NOTE: This clause is applicable to all solicitations and resultant contracts calling for maintenance, calibration, and/or repair of information technology, scientific and medical, and office and business equipment if the contracting officer determines that the resultant contract may be exempt from Service Contract Act coverage).

(a) The following certification shall be checked:

CERTIFICATION

The offeror certifies **[ ]**, does not certify **[ ]** that: (1) The items of equipment to be serviced under this contract are commercial items which are used regularly for other than Government purposes, and are sold or traded by the Contractor in substantial quantities to the general public in the course of normal business operations; (2) The contract services are furnished at prices which are, or are based on, established catalog or market prices for the maintenance, calibration, and/or repair of certain information technology, scientific and medical, and/or office and business equipment. An "established catalog price" is a price (including discount price) recorded in a catalog, price list schedule, or other verifiable and established record that is regularly maintained by the manufacturer or the Contractor and is either published or otherwise available for inspection by customers. An "established market price" is a current price, established in the usual course of ordinary and usual trade between buyers and sellers free to bargain, which can be substantiated by data from sources independent of the manufacturer or Contractor; and (3) The Contractor utilizes the same compensation (wage and fringe benefits) plan for all service employees performing work under the contract as the Contractor uses for equivalent employees servicing the same equipment of commercial customers.

(b) If a negative certification is made and a Service Contract Act wage determination is not attached to the solicitation, the Contractor shall notify the Contracting Officer as soon as possible.

(c) Failure to execute the certification in paragraph (a) of this clause or to contact the Contracting Officer as required in paragraph (b) of this clause may render the bid or offer nonresponsive.

16. **52.223-1 CLEAN AIR AND WATER CERTIFICATION (APRIL 1984)**

(Note: Applicable to contracts expected to exceed $100,000. Not Applicable for contracts with commercial items.)

The Offeror certifies that --

(a) Any facility to be used in the performance of this proposed contract is **[ ]**, is not **[ ]** listed on the Environmental Protection Agency List of Violating Facilities;

(b) The Offeror will immediately notify the Contracting Officer, before award, of the receipt of any communication from the Administrator, or a designee, of the Environmental Protection Agency, indicating that any facility that the offeror proposes to use for the performance of the contract is under consideration to be listed on the EPA List of Violating Facilities; and

(c) The Offeror will include a certification substantially the same as this certification, including this paragraph (c), in every nonexempt subcontract.

17. **52.223-4 RECOVERED MATERIAL CERTIFICATION (OCTOBER 1997)**

(This certification is applicable in solicitations that are for, or specify the use, of recovered materials.)

As required by the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6962(c)(3)(A)(i)), the offeror certifies, by signing this offer, that the percentage of recovered materials to be used in the performance of the contract will be at least the amount required by the applicable contract specifications.

18. **52.223-13 CERTIFICATION OF TOXIC CHEMICAL RELEASE REPORTING (OCTOBER 1996)**

NOTE: This certification is applicable for all solicitations for competitive contracts expected to exceed $100,000 (including all options) and competitive 8(a) contracts. It is not applicable to acquisitions of commercial items, or to contracts where the contractor's facilities are located outside the United States (the "United States" includes any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, and any other territory or possession over which the United States has jurisdiction)

(a) Submission of this certification is a prerequisite for making or entering into this contract imposed by Executive Order 12969, August 8, 1995.

(b) By signing this offer, the offeror certifies that--

(1) As the owner or operator of facilities that will be used in the performance of this contract that are subject to the filing and reporting requirements described in section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106), the offeror will file and continue to file for such facilities for the life of the contract the Toxic Chemical Release Inventory Form (Form R) as described in sections 313(a) and (g) of EPCRA and section 6607 of PPA; or

(2) None of its owned or operated facilities to be used in the performance of this contract is subject to the Form R filing and reporting requirements because each such facility is exempt for at least one of the following reasons: (Check each block that is applicable.)

[ ] (i) The facility does not manufacture, process, or otherwise use any toxic chemicals listed under section 313(c) of EPCRA, 42 U.S.C. 11023(c);

[ ] (ii) The facility does not have 10 or more full-time employees as specified in section 313(b)(1)(A) of EPCRA, 42 U.S.C. 11023(b)(1)(A);

[ ] (iii) The facility does not meet the reporting thresholds of toxic chemicals established under section 313(f) of EPCRA, 42 U.S.C. 11023(f) (including the alternate thresholds at 40 CFR 372.27, provided an appropriate certification form has been filed with EPA);

[ ] (iv) The facility does not fall within Standard Industrial Classification Code (SIC) designations 20 through 39 as set forth in Section 19.102 of the ion Regulation; or

[ ] (v) The facility is not located within any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, or any other territory or possession over which the United States has jurisdiction.

19. **52.225-1 BUY AMERICAN CERTIFICATE (DECEMBER 1989)**

The offeror certifies that each end product, except those listed below, is a domestic end product (as defined in the clause entitled "Buy American Act - Supplies"), and that components of unknown origin are considered to have been mined, produced, or manufactured outside the United States.

Excluded End Products	Country of Origin
_____	_____
_____	_____
_____	_____
_____	_____

(List as necessary.)

Offerors may obtain from the contracting officer lists of articles, materials, and supplies excepted from the Buy American Act.

20. **52.225-6 BALANCE OF PAYMENTS PROGRAM CERTIFICATE - (APRIL 1985)**

(NOTE: To be completed only for offers for services at or greater than $100,000, (and for construction between $100,000 and $7,310,999) for use outside the U.S.

(a) The offeror hereby certifies that each end product or service, except the end products or services listed below, is a domestic end product or service (as defined in the clause entitled "Balance of Payments Program") and that components of unknown origin have been considered to have been mined, produced, or manufactured outside the United States.

Excluded End Products

Line Item Number	Country of Origin

(b) For evaluation purposes only, each offer of an end product other than a domestic end product shall be increased by 50 percent. Any domestic end product offer that exceeds such evaluated other end product shall be considered unreasonable in cost or inconsistent with the public interest.

21. **52.225-8 TRADE AGREEMENTS ACT CERTIFICATE (DEVIATION)**

(**Note: Applies to offers for supplies greater than $190,000)**

(a) The offeror hereby certifies that each end product to be delivered under this contract is a U.S. made end product, a designated country end product, a North American Free Trade Agreement (NAFTA) country end product, or a Caribbean Basin country end product as defined in the clause entitled "Trade Agreements Act" FAR 52.225-9 (Deviation).

(b) Offers will be evaluated in accordance with Subpart 25.4 of the Federal Acquisition Regulation except that offers of U.S. made end products shall be evaluated without the restrictions of the Buy American Act or the Balance of Payments Program.

22. **52.225-20 BUY AMERICAN ACT - NORTH AMERICAN FREE TRADE AGREEMENT IMPLEMENTATION ACT - BALANCE OF PAYMENTS PROGRAM CERTIFICATE - (JANUARY 1997)**

(NOTE: To be completed for offers subject to the North American Free Trade Agreement Act, but not subject to the Trade Agreements Act - e.g., those offers for supplies between $25,000 and $189,999.)

(a) The offeror certifies that each end product being offered, except those listed in paragraph (b) of this provision, is a domestic end product (as defined in the clause entitled "Buy American Act - North American Free Trade Agreement Implementation Act - Balance of Payments Program"). Components of unknown origin have been considered to have been mined, produced, or manufactured outside the United States.

(b) Excluded End Products:

Line Item Number	Country of Origin

(List as Necessary)

(c) Offerors will be evaluated by giving certain preferences to domestic end products or NAFTA country end products over other end products. In order to obtain these preferences in the evaluation of each excluded end product listed in paragraph (b) of this provision, offerors must identify and certify below those excluded end products that are NAFTA country end products. Products that are not identified and certified below will not be deemed to be NAFTA country end products.

The offeror certifies that the following supplies qualify as "NAFTA country end products" as that term is defined in the clause entitled "Buy American Act - North American Free Trade Agreement Implementation Act - Balance of Payments Program."

Line Item Number	Country of Origin
_____	_____
_____	_____
_____	_____

(List as Necessary)

(d) Offers will be evaluated in accordance with Part 25 of the Federal Acquisition Regulation. In addition, if this solicitation is for supplies for use outside the United States, an evaluation factor of 50 percent will be applied to offers of end products that are not domestic or NAFTA country end products.

ALTERNATE I (JANUARY 1997)

(NOTE: Applies when the acquisition value is between $25,000 and $50,000 and it is not subject to the Trade Agreements Act but is subject to NAFTA.)

As prescribed in 25.408(a)(3), substitute the following paragraph (c) for paragraph (c) of the basic provision:

(c) Offers will be evaluated by giving certain preferences to domestic end products or Canadian end products over other end products. In order to obtain these preferences in the evaluation of each excluded end product listed in paragraph (b) of this provision, offerors must identify and certify below those excluded end products that are Canadian end products. Products that are not identified and certified below will not be deemed Canadian end products.

The offeror certifies that the following supplies qualify as "Canadian end products" as that term is defined in the clause entitled "Buy American Act-North American Free Trade Agreement Implementation Act-Balance of Payments Program":

_____

(Insert line item numbers)

23. **52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION - (MAY 1997)**

(a) Definitions. As used in this provision--Historically Black College or University means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration, and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

Minority Institution means an institution of higher education meeting the requirements of Section 1046(3) of the Higher Education Act of 1965 (20 U.S.C. 1135d-5(3)) which, for the purpose of this provision, includes a Hispanic-serving institution of higher education as defined in Section 316(b)(1) of the Act (20 U.S.C. 1059c(b)(1)).

(b) Representation. The offeror represents that it--

[ ] is **[ ]** is not a Historically Black College or University;

[ ] is **[ ]** is not a Minority Institution.

24. **52.227-6 ROYALTY INFORMATION - (APRIL 1984)**

(a) **Cost or charges for royalties.** When the response to this solicitation contains costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers, patent application serial numbers or other basis on which the royalty is payable.
(4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
(5) Percentage or dollar rate of royalty per unit.
(6) Unit price of contract item.
(7) Number of units.
(8) Total dollar amount of royalties.

(b) **Copies of current licenses**. In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

(**NOTE: Alternate I, below, is applicable for communication services and facilities by a common carrier.)**

ALTERNATE I (APRIL 1984), 52.227-6 ROYALTY INFORMATION (APRIL 1984)

Substitute the following for the introductory portion of paragraph (a) of the basic clause:

When the response to this solicitation covers charges for special construction or special assembly that contain costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

25. **52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (APRIL 1998)**

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48 CFR 9903.201-2(C)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement -- Cost Accounting Practices and Certification

(a) Any contract in excess of $500,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

[ ] (1) Certificate of Concurrent Submission of Disclosure Statement.

The offeror hereby certifies that, as part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) original and one copy to the cognizant Administrative Contracting Officer (ACO), or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and;
(ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable.. Forms may be obtained from the cognizant ACO or Federal official and/or from the looseleaf version of the Federal Acquisition Regulation).

Date of Disclosure Statement: _____

Name and Address of Cognizant ACO or Federal Official Where Filed: _____

_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

[ ] (2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____

Name and Address of Cognizant ACO or Federal Official Where Filed: _____

_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

[ ] (3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than $25 million (of which at least one award exceeded $1 million) in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

[ ] (4) Certificate of Interim Exemption.

The offeror hereby certifies that:

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted, and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $25 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

[ ] (5) Certificate of Disclosure Statement Due Date by Educational Institution.
(ALTERNATE I - APRIL 1996)

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903-202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (***check one and complete***):

[ ] (i) A Disclosure Statement filing Due Date of _____ has been established with the cognizant Federal agency.

[ ] (ii) The Disclosure Statement will be submitted within the 6-month period ending _____ months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Disclosure Statement is to be Filed: _____

_____

II. Cost Accounting Standards -- Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

[ ] The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $25 million in awards of CAS-covered prime contracts and subcontracts, or the offeror did not receive a single CAS-covered award exceeding $1 million. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $25 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $25 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards Clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

[ ] YES **[ ]** NO

26. **CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (DECEMBER 1994)**

(Note: This certification applies only to those contract which contain provisions for children's services. The offeror's signature on the face page of these Representations and Certifications constitutes certification by the submitting organization of its compliance with the Act.)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this certification, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

27. **CERTIFICATION OF INSTITUTIONAL POLICY ON CONFLICT OF FINANCIAL INTEREST (OCTOBER 1995)**

(Note: This certification is applicable to Research and Development (R&D) Contracts. However, this certification does not apply to SBIR-Phase I contractors.)

By submission of its offer, the offeror certifies that:

(1) A written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interest with respect to all research projects for which funding is sought from the NIH is **[ ]**, is not **[ ]** currently in effect.

(2) Should a process not be in effect at the time of the submission of its offer, the offeror certifies that it will, no later than 30 days subsequent to submission of its offer or prior to award, whichever is earlier, notify the Contracting Officer of the establishment of a written and enforced financial conflict of interest policy.

28. **15.406-2 CERTIFICATE OF CURRENT COST OR PRICING DATA**

(When cost or pricing data are required in accordance with FAR 15.406-2, the Contracting Officer will request that the offeror complete, execute, and submit to the Contracting Officer a certification in the format shown in the following Certificate of Current Cost or Pricing Data. The certification shall be submitted only at the time negotiations are concluded. Offerors should complete the certificate and return it when requested by the Contracting Officer.)

This is to certify that, to the best of my knowledge and belief, the cost or pricing data (as defined in section 15.401 of the Federal Acquisition Regulation (FAR) and required under FAR subsection 15.403-4) submitted, either actually or by specific identification in writing, to the Contracting Officer or to the Contracting Officer's representative in support of _____* are accurate, complete, and current as of_____**.

This certification includes the cost or pricing data supporting any advance agreements and forward pricing rate agreements between the offeror and the Government that are part of the proposal.

Firm _____

Signature _____

Name _____

Title _____

Date of execution*** _____

* Identify the proposal, request for price adjustment, or other submission involved, giving the appropriate identifying number (e.g., RFP No.)

** Insert the day, month, and year when price negotiations were concluded and price agreement was reached, or, if applicable, an earlier date agreed upon between the parties that is as close as practicable to the date of agreement on price.

*** Insert the day, month, and year of signing, which should be as close as practicable to the date when the price negotiations were concluded and the contract price was agreed to.

(End of Certificate)