SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
▶		1 of 24

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	RFP NHLBI-HR-99-02	☐ SEALED BID (IFB) ☑ NEGOTIATED (RFP)	1/27/99	

7. ISSUED BY CODE

National Heart, Lung, & Blood Institute, NIH
Rockledge 2, Room 6114
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

8. ADDRESS OFFER TO *(If other than Item 7)*

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 20* 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] *See page 13 until 4:30 pm (Hour) local time 03/22/1999 (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
	Joanne C. Deshler	301	435-0340	NA	jd52g@nih.gov

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

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

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 300 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 contract is to provide scientific and statistical expertise to support a multi-center research study. Feasibility studies will be conducted at 4-5 clinical centers on the use of retinoids in the treatment of emphysema. The specific objectives of the program are to identify optimal patient populations, retinoids, doses, dosing schedules, routes of administration, and outcome measures on the efficacy of retinoid therapy in the management of emphysema.

ARTICLE B.2. ESTIMATED COST

a. The estimated cost of this contract is $X.

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

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

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

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

Period			Amount
09/30/99	-	03/31/99	$X
04/01/99	-	03/31/00	$X
04/01/00	-	03/31/01	$X
04/01/01	-	09/29/01	$X

SECTION C—DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

(Note to Offerors: For a complete description of the Background and History, Objectives, and Committees refer to Section L., Part III below. Whenever reference is made to study protocols or studies, it means the contractor's proposed protocol or study.)

ARTICLE C.1. STATEMENT OF WORK

Independently, and not as an agent of the Government, the contractor shall furnish all the necessary services, qualified personnel with expertise in pulmonary medicine, retinoid therapy, clinical trial design, statistics, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

PHASE I - September 30, 1999 - March 31, 2000

a. Participate in a cooperative effort with investigators from the Clinical Centers (CCs) and representatives of the NHLBI to form a Steering Committee. Contribute to committees established by the Steering Committee. The members of the Steering Committee will decide on the number and type of subcommittees that are needed to direct this program.

b. Provide administrative leadership and scientific coordination for the development of study protocols. Participate in a cooperative effort with the CC investigators and the program office staff in all aspects of the study, including making the protocols comparable and complementary. Work with the CC investigators to develop common definitions, standardization of common procedures, and development of compatible data forms. Take lead responsibility in developing those portions of the protocols concerned with the statistical analyses for each study individually and across studies.

c. Participate in the Steering Committee effort to develop a manual of operations.

d. Develop the computer software used to process, store and analyze the study data. Develop, test, and implement a method for transmitting data from the CCs. Develop, standardize, test, print, and distribute all data reporting forms for each study. Ensure data are comparable across studies. Purchase and install at each participating clinical center the computer systems that will be used to enter and transmit data between the clinical centers and the clinical coordinating center, should a distributed data entry system be proposed.

e. Prepare, reproduce, and distribute to the Steering Committee and the NHLBI study documents, including draft copies of the protocol and manual of operations.

f. Develop the biostatistical portions of the protocol including study design, power and sample size calculations, and an interim monitoring and analysis plan. Biostatistical portions shall include data analyses within each study protocol and across all studies.

g. Plan, prepare the agendas for, coordinate, participate in, and make all arrangements for the meetings and calls of the Steering Committee and Data and Safety Monitoring Board. Produce and distribute minutes of the Steering Committee meetings to the Project Officer and Steering Committee members.

h. Establish and train the staff at CCs and at own center in data collection, transmission, management, and common protocol procedures as outlined in the study protocol and manual of operations.

i. The study protocols shall be reviewed by a Data and Safety Monitoring Board (DSMB) prior to implementation. The DSMB will be appointed by the NHLBI and shall make a recommendation to the NHLBI regarding the final study protocols. The final study protocols shall be developed, approved, and implemented prior to March 31, 2000.

The Contractor shall not begin work on Phase II activity until written approval has been received from the Contracting Officer.

PHASE II - April 1, 2000 - March 31, 2002

j. Participate with CC investigators in Steering Committee meetings and other study operations in accordance with the protocols and manual of operations. Work cooperatively with CC investigators in reporting study data collected.

k. Plan, prepare the agendas for, coordinate, participate in, and make all arrangements for the meetings and calls of the Steering Committee and Data and Safety Monitoring Board. Produce and distribute minutes of the Steering Committee meetings to the Project Officer and Steering Committee members.

l. Serve as the repository for the clinical data collected during Phase II. Assume primary responsibility to assure CCs forward data in accordance with an established time schedule.

m. Monitor recruitment into each study for numbers, adherence to targeted patient population, gender and ethnicity. Submit to the Project Office and the CCs recruitment reports and statistical data reports.

n. Process and store all clinical data on a computer and present the data in printed and/or graphic form at study meetings and in technical reports.

o. Maintain computer software necessary to process, store and analyze data furnished by the CCs.

p. Maintain a liaison with each CC to assist in the solution of operational problems involved in data collection and reporting. Assist CC staff in data management and administrative functions such as scheduling and tracking subjects.

q. Review and ensure completeness, accuracy, and quality control of study data. Ensure that quality control of data is maintained during collection and prior to processing. Quality control shall include the following: 1) pursue missing data and correctable errors by communication with CCs; 2) maintain an audit trail of data entry and data corrections; 3) review collected data on a regular basis to verify completeness; 4) review adherence to schedules for reexaminations and other data collection on a regular basis, and 5) re-certify CC staff as needed in examination procedures, interviews, and data entry and editing.

r. Prepare statistical reports that detail study progress, quality of data, and CC performance. Prepare and distribute periodic technical reports to the Data and Safety Monitoring Board Members, the Project Officer and the Contracting Officer.

s. Establish a mechanism for on-site monitoring of patient records in order to validate the data collected and transmitted. Coordinate and participate in periodic CC site visits to monitor center operations and quality of study data.

t. Prepare study progress reports for the Data and Safety Monitoring Board. These reports shall address data collection, quality control of data, recruitment and performance of each CC.

u. Assume responsibility for the timely completion of data analyses. Work with each CC investigator to provide the most appropriate and effective approaches for analyzing the data to address specific issues related to the objectives of each study and the aggregate program.

v. Work with other study investigators in the reporting of data, preparation, and writing of reports and manuscripts for publication.

PHASE III - April 1, 2002 - September 29, 2002

w. Interact with the CC investigators to provide the design and statistical information necessary for analyzing the data to address goals of each study and of the program. Complete data analysis and preparation for publication of final outcomes of each study and of the program.

x. Work with other study investigators in the preparation and writing of reports and manuscripts for publication.

y. Provide one copy of the program data set with full documentation. The documentation shall be clear and allow for use by investigators not familiar with the data set.

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:

Technical Reports

a. **Protocol and Manual of Operations**: This shall include all draft versions and the final approved protocol and manual of operations and any amendments thereto.

b. **Recruitment Report**: During Phase II the contractor shall submit monthly reports. Recruitment reports shall describe the progress of recruitment at each CC and activities as defined by the study protocol and manual of operations.

c. **Statistical/Data Report**: During Phase II, the contractor shall describe all work accomplished during the preceding months, beginning with the first full quarter of performance including any fractional part of the initial month. This report shall include recruitment activities, follow-up data, quality of data, CC performance, participant enrollment, forms completion rates, response variables and adverse reactions in accordance with the study protocol and manual of operations. The reporting shall indicate which data were collected and whether the subject was seen within the window defined by the study protocol.

d. **Study Population Report**: During Phase II, the Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each clinical center study. This information shall be submitted in the format indicated in the Attachment entitled, "Annual Technical Progress Report Format for Each Study".

e. **Annual Report**: A comprehensive annual report reflecting all activities conducted during the contract year shall be submitted on each anniversary date following award. This report shall be written in sufficient detail to allow use as a reference document. The annual reports shall include but not be limited to:

   i. A cover page containing the following information:
      1. Contract number
      2. Contractor's name and address
      3. Principal investigator
   ii. Description of overall progress.
   iii. Current problems which may impede performance and proposed corrective action.
   iv. Work to be performed during the next year, by protocol.

   Each report shall be in a narrative form, concise and informational and shall include a “Table of Contents” and bibliographies, tabular material and exhibits, as necessary. Extensive reference material is not desired, but such references as are necessary to full understanding may be included.

f. **Final Report**: This report shall 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 and shall be in sufficient detail to serve as a reference document.

g. **Computer Data Set**: This shall include the study data with full documentation. The documentation shall allow for use by investigators not familiar with the data set. The documentation shall be written Word Perfect or ASCII format, and shall be prepared in accordance with the NHLBI Public Use Data Clause–Clinical Coordinating Center.

h. **Draft Steering Committee (SC) Meeting Minutes**: Draft minutes from each Steering Committee meeting shall be provided to the Project Officer for review and comment two (2) weeks after meeting.

i. **Final Steering Committee (SC) Meeting Minutes**: Final minutes shall be prepared and distributed to Steering Committee members four (4) weeks after each meeting.

Other Deliverables:

j. **Abstracts and manuscripts** proposed for publication shall be provided in accordance with the study protocol and manual of operations.

k. **Optional Form 310**: Documentation of IRB approval shall be provided at the completion of Phase I, and annually thereafter.

l. **Financial Reports**: Quarterly financial reports which summarize the status of costs incurred under the contract shall be prepared in accordance with "Instructions for Completing, Form NIH 2706." Financial reports will not be required for contracts submitting regular monthly invoices.

m. **SF 294 Report**: Subcontracting Report for Individual Projects shall be submitted semi-annually.

SECTION D—PACKAGING, MARKING, AND SHIPPING

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

SECTION E—INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance will be performed at: National Institutes of Health, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 6016, ROCKLEDGE BUILDING (RKL2) MSC 7902, BETHESDA, MD 20892-7902.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE: 52.246-9,
INSPECTION OF RESEARCH AND DEVELOPMENT - (SHORT FORM) (APRIL 1984).

SECTION F—DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERABLES

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

The items specified below as described in SECTION C, ARTICLE C.2. shall be delivered f.o.b. destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES (APRIL 1984) and in accordance with and by the date(s) specified below and any specifications stated in SECTION D. - PACKAGING, MARKING, AND SHIPPING, of this contract:

Item	Description	Delivered to:	Delivery Schedule
a.	Protocol and Manual of Operations	Contacting Officer Project Officer SC Members DSMB Members	On or before March 31, 2000
b.	Recruitment Report	Contracting Officer Project Officer	Monthly During Phase II
c.	Statistical/Data Report	Contracting Officer Project Officer DSMB Members	Quarterly During Phase II
d.	Study Population Report	Contracting Officer Project Officer	Annually During Phase II
e.	Annual Report	Contracting Officer Project Officer	On Anniversary Date
f.	Final Report	Contracting Officer Project Officer	Upon Completion of Contract
g.	Computer Data Set	Contracting Officer	Upon Completion of Contract
h.	Draft SC Minutes	Project Officer	Two weeks after SC Meeting
i.	Final SC Minutes	Contracting Officer Project Officer SC Members	Four weeks after SC Meeting
j.	Abstracts & Manuscripts	Contracting Officer Project Officer SC Members DSMB Members	Prior to Publication
k.	Optional Form 310	Contracting Officer	End of Phase I and Annually During Phase II

Item	Description	Delivered to:	Delivery Schedule
l.	Financial Report	Contracting Officer	Quarterly
m.	SF 294 Report	Contracting Officer	Semi Annually

Deliverables shall be sent to the following addresses:

Address	Item	Quantity
Project Officer Division of Lung Diseases, NHLBI 6701 ROCKLEDGE DR MSC 7952 BETHESDA MD 20892-7952	a.– f., h.–j.	1 each
Contracting Officer Contracts Operations Branch DEA, NHLBI 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902	a. – g., i.–m.	1 each
DSMB Members (To be identified)	a., c., j.	1 each
Steering Committee Members (To be identified)	a., i., j.	1 each

SECTION G—CONTRACT ADMINISTRATION DATA

(NOTE: See **?**Sample Contract Format – General" for potential Section G. Articles which will be accessed at the following web site: **http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm.**)

SECTION H—SPECIAL CONTRACT REQUIREMENTS

(NOTE: See **?**Sample Contract Format – General" for potential Section H. Articles which will be accessed at the following web site: **http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm**.)

PART II— CONTRACT CLAUSES

SECTION I—CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT [Educational, Nonprofit, or other depending on organizational status of offeror; selected appropriate article]— CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998) (NOTE: The following section for General Clause Listing can be accessed at the following web site: **http://rcb.nci.nih.gov/Clauses/Clauses.html**.)

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

a. ALTERNATE I of FAR Clause 52.216-11, COST CONTRACT - NO FEE (APRIL 1984) is added.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

(1) FAR 52.224-1, Privacy Act Notification (APRIL 1984)
(2) FAR 52.224-2, Privacy Act (APRIL 1984)
(3) FAR 52.243-2, Changes-Cost Reimbursement (AUGUST 1987). Alternate V (APRIL 1984)
(4) FAR 52.230-5, Cost Accounting Standards, Educational Institution (APR 1996).
(5) FAR 52.230-6, Administration of Cost Accounting Standards (APR 1996).

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

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

(1) PHS 352.280-1b, Protection of Human Subjects (OCTOBER 1986).

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

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

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

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

a. NHLBI Public Use Data Clause - Clinical Trial Coordinating Center

Public use data will be released under this clinical trial. After publication of the primary clinical trial results, the coordinating center shall prepare the data and deliver it to the NHLBI in a format suitable for use by the public. Such release is expected to occur no later than three years after the primary publication. The contractor shall provide the data to the NHLBI within two years of the primary publication so that the NHLBI can check the data before release. This will allow for the NHLBI review, discussion of the data, and opportunity for any changes needed in content or presentation prior to release. If the contract expiration date does not allow the contractor to comply with the above time frame, the data shall be prepared and delivered at least thirty days prior to the contract expiration date.

The public use data set will include the baseline visit, interim visit(s), and outcome data, including laboratory measurements. Inclusion of raw data that has been processed into summary information shall be discussed with the Project Officer prior to submission. Data

prepared for release shall not contain personal identifiers. The contractor shall coordinate preparation of the data with the NHLBI to assure patient confidentiality. The data shall be submitted on CD ROM, or other mutually agreed upon data medium that includes complete electronic documentation and data.

Ancillary study data (not funded under this contract) are not required to be included in the public use data set, though the data may be included if agreed upon by the ancillary study investigator.

The contractor shall produce clear documentation for the public use data. The documentation must allow for use by investigators not familiar with the data set. The documentation must be written in WordPerfect or ASCII format, and must be included as a data set in the storage medium.

The study investigators will be expected to answer questions regarding data set characteristics, format and content, during the study. Documentation is expected to be of the highest quality so that such questions will be minimized.

Data will not be prepared for public use if the investigators and NHLBI believe that they are unreliable or invalid. These exceptions must be justified in writing to the NHLBI and will be reviewed and, if the NHLBI concurs, will be approved in writing by the Director of the Division that sponsored the trial.

b. Year 2000 Warranty - Non-commercial Supply Items

The contractor warrants that each non-commercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries, including leap-year calculations, when used in accordance with the item documentation provided by the contractor, provided that all listed or unlisted items (e.g., hardware, software, firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and conditions of any general warranty provisions of this contract, provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose non-compliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

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

SECTION J—LIST OF ATTACHMENTS

See listing of RFP and Contract attachments in Section L, Part III 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 available at: **http://www4.od.nih.gov/ocm/contracts/rfps/REPCERT.htm**. Please see also the instructions for the attached form in the listing of RFP and Contract attachments in Section L, Part III below.

SECTION L—INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

THIS SECTION OF THE RFP CONSISTS OF THE FOLLOWING SECTIONS:

I. Specific RFP Instructions and Provisions, (pages 11–17)

II. Applicable RFP References, and (pages 17–18)

III. Project Information (pages 19–23)

I. 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 by February 22, 1999)

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 and Travel

F. Service of Protest

G. Technical Proposal Table of Contents

H. Page Limits

I. Other Provisions

J. Special Requirements

K. Restrictions

L. References

A. PROPOSAL INTENT RESPONSE SHEET

RFP No. NHLBI-HR-99-02

TITLE OF RFP: Clinical Coordinating Center for Feasibility Studies on Retinoid Treatment in Emphysema

FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY **February 22, 1999**. 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:

Attention: Dr. James Scheirer
Review Branch
NIH, NHLBI
6701 ROCKLEDGE DR MSC 7924
BETHESDA MD 20892-7924

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-HR-99-02
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 (20) COPIES

BUSINESS PROPOSAL: ORIGINAL* AND Five (5) 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 1 award will be made from this solicitation and this award will be made on/about September 30, 1999. It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type completion contract with a period of performance September 30, 1999 to September 29, 2002.

E. LEVEL OF EFFORT AND TRAVEL

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 during various phases of the study. (Thus in 6 month Phase I, 20% effort reflects 10% person year of effort).

Labor Category	Phase I (6 months)	Phase II (up to 24 months)	Phase III (6 months)
Biostatistician	25%	25%	25%
Pulmonary	20%	25%	25%
Sr. Statistician	40%	60%	60%
Systems Analyst	30%	50%	30%
Programmer	20%	75%	50%
Data Manager	20%	50%	40%
Data Coordinator	25%	25%	25%
TOTAL	180%	310%	255%

Travel: Travel expenses should be based on attending Steering Committee and Data and Safety Monitoring Board meetings in Bethesda, Maryland.

During Phase I: costs will be allowed for the effort of three investigators. Travel expenses should be based on three meetings (2 days each). The CCC shall budget for the training of the Clinic Coordinators in study operations at the conclusion of Phase I. The PI and one investigator will attend one DSMB meeting to report on the Protocol and Manual of Operations developed.

Phase II (24 Months): costs will be allowed for three investigators to attend two Steering Committee meetings twice a year. Travel to attend these meetings should be based on 1 day. The PI and one investigator will attend DSMB meetings twice a year to present study data to the members.

Phase III (6 Months): costs will be allowed for three investigators to attend two Steering Committee meetings. Travel to attend these meetings should be based on 2 days. The PI and one investigator will attend one DSMB meeting to present the study data and report on the publications and manuscripts.

F. SERVICE OF PROTEST

In accordance with FAR 52.233-2 SERVICE OF PROTEST (AUG 1996):

(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. Joanne C. Deshler

Address:
National Institutes of Health
National Heart, Lung, and Blood Institute
Contracts Operations Branch
Rockledge 2, Room 6114
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the 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 objectives. 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 . . . . . Page 4

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 TWO-PAGE BIOSKETCHES FOR INVESTIGATORS AND NARRATIVES, INCLUDING ROLE IN PROGRAM, EXPERTISE, AND RELATED EXPERIENCES, FOR:

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

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

(4) Additional Personnel . . . . . Page #

B. PROPOSED APPROACH (no more than 50 PAGES single-spaced)

(1) Objectives . . . . . Page #

(2) Approach . . . . . Page #

(3) Methods and Procedures . . . . . 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/DOCUMENTATION . . . . . Page #

(1) Documentation of submission to IRB of protocol and consents

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 #

The form is located in the Streamlined RFP References under "FORMS, FORMATS, & ATTACHMENTS."

7. LITERATURE CITED . . . . . Page #

8. APPENDICES . . . . . Page #

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.

H. Page Limits

The technical proposed approach (Section 4B, above) shall be limited to 50 pages single-spaced. The cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, other support, cost information, and literature cited do not count against the 50 page limit. Appendices shall be limited to 100 pages single-spaced.

I. OTHER PROVISIONS

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 Heart, Lung, and Blood Institute, National Institutes of Health, under Contract No. . . .

J. SPECIAL REQUIREMENTS

a. CAPITATION/CLINICAL REIMBURSEMENT

A capitation reimbursement system for the clinical center contractors will be discussed and developed during Phase I. Individual clinic capitation rates would likely be based on their negotiated patient care costs and the projected recruitment goals and their accomplishment. Reimbursement of capitation costs would only be made after the Clinical Coordinating Center has verified to the Contracting Officer that the required data are complete and accurate.

b. OMB CLEARANCE

A clinical exemption for the forms for this project will be coordinated by the NHLBI and NIH Project Clearance Officers at the completion of Phase I. It is expected that the forms used to collect clinical data under this study will be exempt from OMB clearance requirements.

c. GOVERNMENT FURNISHED MATERIAL/FACILITIES

The Clinical Coordinating Center will be responsible for the purchase and installation of the hardware and software that may be necessary at each clinical center for distributed data entry, if such a method is proposed. The Government will not be responsible for the purchase of any hardware and software at the Clinical Coordinating Center that may be necessary to carry out the statement of work.

d. SMALL DISADVANTAGED BUSINESS CONCERNS

This solicitation will consider the offeror's inclusion of the participation of Small Disadvantaged Business (SDB) concerns in the performance of the contract. Offerors are encouraged to include participation of SDB concerns, where possible, in their proposal. Offerors shall include in their proposal a specific explanation of whether SDB concerns can be utilized in performing the contract work.

Proposals, included in the competitive range, will be reviewed to determine the extent to which the offeror identified specific SDB concerns and the extent of commitment to use these SDB concerns in the performance of the contract. The extent of this participation may be discussed with those offerors whose proposals are included in the competitive range.

K. RESTRICTIONS

a. In order to ensure that data analysis is done independently of data acquisition, an award to a Clinical Center and a Clinical Coordinating Center under this RFP shall not be made to the same Principal Investigator. The same institution may apply for both a Clinical Center and a Clinical Coordinating Center award provided they have no investigators in common.

b. It is to be noted that the award of contracts under this RFP shall be made only to offerors who are located in the United States of America. Proposals received from offerors located outside of the United States of America will not be considered for a contract award. There are several reasons for this determination. In order for the work of this multi-center program to perform successfully, it shall be necessary for the Clinical Coordinating Center (CCC) to maintain a close and effective working relationship with the Clinical Centers, which are expected to be located predominantly in the United States. This includes holding frequent meetings and conduction of site visits. This requires that the CCC be located within the United States.

L. REFERENCES

Massaro, GD and Massaro D. Retinoic Acid Treatment Abrogates Elastase-induced Pulmonary Emphysema in Rats. *Nature Med* 3:675-677, 1997

II. 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 WITHDRAWALS OF PROPOSALS, PHS 352.215-10

F. Human Subjects

H. Small, Small Disadvantaged, and Women-Owned Small Business Subcontracting Plan

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:

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

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

3. 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.

4. Representations and Certifications, with original.

OTHER--TO BE SUBMITTED LATER:

1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with Final Proposal Revision, as directed by the Contracting Officer.

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

l. Invoice/Financing for Cost Reimbursement Type Contracts, NIH(RC)-1

2. Procurement of Certain Equipment, NIH(RC)-7
3. NIH 2706, Financial Report for Individual Project/Contract Instructions
4. NIH 2706, Financial Report for Individual Project/Contract Form
5. Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF 310
6. Annual Technical Progress Report Format for Each Study

D. The "SAMPLE CONTRACT FORMAT-GENERAL" is applicable.

III. Project Information

a. Background and History

Chronic obstructive pulmonary disease (COPD), which includes chronic bronchitis and emphysema, affects more than 16 million Americans, is the fourth leading cause of death in the USA, and costs the nation billions in direct and indirect health care costs. Though only about two million of the 16 million people with COPD have emphysema, emphysema is more disabling, accounting for approximately half of the 114 million days of restricted activity and half of the 53 million days of disability attributed to COPD per year. Emphysema is characterized by destruction of the airspace walls, leading anatomically to abnormal, persistent enlargement of the airspaces distal to the terminal bronchioles, and without obvious fibrosis. The clinical result is continuous dyspnea due to hyperinflation of the lung, over distention of the chest wall, disadvantaged respiratory muscles, and hypoxia, even at rest.

Treatment options in emphysema are limited and primarily aimed at symptomatic relief of the dyspnea by maximizing the depleted reserves of the patient. In the late stages, care is supportive, in the form of oxygen therapy, bronchodilator, nutritional supplementation and exercise rehabilitation. Exercise rehabilitation has been shown to improve the quality of life, but only oxygen therapy has been shown to affect survival. For patients less than 60 years old, lung transplantation may be possible, but scarcity of donor lungs and expense greatly limits this option and the efficacy has not been studied. Lung volume reduction surgery is currently under investigation for its effect on symptoms and survival. For the few patients with hereditary alpha-1-antitrypsin deficiency, the recent report of the NHLBI supported Alpha-1-Antitrypsin Deficiency Registry Study Group cautions that although those with moderate airflow obstruction may benefit from augmentation therapy, more studies were needed to draw firm conclusions and to answer questions about dose and dosing schedules.

Recent laboratory data have shown that all-*trans*-retinoic acid, a derivative of vitamin A, can regenerate alveoli in adult rats with elastase induced emphysema (Massaro, GD and Massaro D. Retinoic Acid Treatment Abrogates Elastase-induced Pulmonary Emphysema in Rats. *Nature Med* 3:675-677, 1997). Based upon the findings that prior to septation, rats have fibroblasts rich in vitamin A storage granules, high concentrations of cellular retinol binding protein, and lung nuclear retinoic acid binding receptors, all of which diminish after septation and the fact that retinoic acid increases the number of alveoli in rats, the investigators reasoned that retinoic acid plays a key role

in septation. Tracheal instillation of elastase into adult rats resulted in an increase in lung volume, a decrease in surface area, and large alveoli as in human emphysema. Intra peritoneal injection of all-*trans* retinoic acid in the elastase-treated rats for 12 days prior to sacrifice reduced the lung volume and increased the surface area to normal.

In addition to the elastase-treated rats, all-*trans*-retinoic acid has been found to induce formation of alveoli in normal rats, in neonatal rats treated with dexamethasone, which prevents septation, in adult tight skin mice, and in fetal mouse lung in culture.

These findings led to interest in the medical community whether adult emphysema patients might get symptomatic relief from treatment with all-*trans*-retinoic acid. In September 1998, the NHLBI convened a workshop, entitled "Clinical Trial Feasibility: All-*trans*-Retinoic Acid for the Treatment of Emphysema", to discuss the feasibility of a clinical trial to test the efficacy of retinoic acid in the treatment of emphysema. The workshop participants agreed that the laboratory findings were exciting, but that a proof of principle study was needed to demonstrate whether the laboratory findings could be applied to humans with emphysema. Since there was adequate information about the dose range and toxicity of retinoids in humans, adequate methods for assessing the extent of emphysema, and adequate methods to assess the biological activity and distribution of retinoids in the human lung, the workshop participants thought studies in emphysema patients were possible and appropriate. Several possible populations and retinoids, especially the retinoic acids, were discussed as appropriate for a clinical trial. However, the participants did not think that there was sufficient information available to recommend a single trial design and recommended the conduct of multiple small trials, allowing flexibility in the choice of population, retinoid, doses, and outcomes.

b. Objective/Desired Result:

The overall objective of this research contract program is to support a multi-center contract program. Clinical Centers awarded a contract will conduct feasibility studies on the use of retinoids in the treatment of emphysema. The specific objectives of the program are to identify optimal patient populations, retinoids, doses, dosing schedules, routes of administration, and outcome measures preparatory to conducting a larger, controlled, clinical trial on the efficacy of retinoid therapy in the management of emphysema, should such a study be indicated. A clinical center awarded a contract will execute its protocol according to the technical approach it has proposed, but will be prepared to accept refinements to make its protocol comparable and complementary to the protocols of other contractors.

The Clinical Coordinating Center will collect, verify, store, and analyze data from each study and across studies under this multi-center program. A separate solicitation has been issued for the Clinical Centers (RFP NHLBI-HR-99-01).

c. Description of Requirement:

The CCC will be responsible for 1) assuming leadership in areas of statistical analyses, including sample size determinations, for each study and across studies; 2) participating in a cooperative effort with the other investigators in the formation of a Steering Committee, development of comparable and complementary protocols, development and testing of compatible reporting forms for each study, and development of the manual of operations; 3) preparing the agendas for, coordinating, and managing the meetings and calls of the Steering Committee, its subcommittees, and the Data and Safety Monitoring Board; 4) preparing and distributing minutes of Steering Committee meetings; 5) standardizing, printing, and distributing reporting forms, the study protocols, and manual of

operations; 6) developing and establishing methods for data entry, data collection, and data transmission and training clinical center staff in these methods; 7) receiving, collecting, processing, storing, and analyzing data collected from the clinical centers; 8) assuring that data is forwarded in accordance with an established time schedule and is reviewed for accuracy and completeness; 9) assuring that quality control is maintained during the collection and processing of all measurements; and 10) describing the progress of the program and program results to the Steering Committee, Program Office, and the Data and Safety Monitoring Board; 11) preparing and distributing periodic technical and statistical reports to the Data and Safety Monitoring Board Members, the Project Officer and the Contracting Officer; and 12) cooperating in the reporting of the data results.

The proposed staff of the CCC must have demonstrated experience in 1) conducting large scale multi-center research studies; 2) working with clinical investigators from multiple sites; 3) the development of study protocols and manual of operations; 4) the monitoring of clinical centers to ensure that data are reviewed for completeness and that quality control is maintained prior to processing, and 5) conducting proper statistical analyses of the data. The staff must have appropriate biostatistical and statistical experience relevant to multi-center clinical research studies. Meta-analysis methodology may be necessary to analyze data across studies. The Principal Investigator must have demonstrated leadership experience in large data management systems, in protocol development for large multi-center studies, and interaction with clinical center investigators from multiple sites. The CCC must have regular commitment of a physician(s) with strong medical and scientific knowledge and experience in care and treatment of patients with emphysema.

The Steering Committee will be composed of the principal investigator from each clinical center, the principal investigator of the Clinical Coordinating Center, and a representative from the Program Office. The Steering Committee will meet twice a year to review progress of the studies. An independent Data and Safety Monitoring Board (DSMB) will be appointed by the NHLBI to oversee the safety of the research protocols and their progress and review results.

d. Offerors must address in their proposal the following requirements relevant to achieving the requirements of the program.

1. Expertise in and plans for participating in a collaborative effort with clinical center investigators and representatives of the NHLBI to form a Steering Committee to direct the study.

2. Expertise in and plans for designing a protocol and manual of operations, and standardizing, printing, and distributing patient forms.

3. Expertise in and plans for developing an appropriate method of data transmission between the clinical centers and the Clinical Coordinating Center.

4. Expertise in and plans for collecting, processing, and storing data from multiple clinical centers and for maintaining the confidentiality of all patient data collected.

5. Plans to monitor and encourage recruitment and prompt and complete data transmission.

6. Expertise in and plans for reviewing and monitoring data to ensure quality control and for assuring that the clinical centers adhere to their protocols.

7. Expertise in and plans for the statistical analysis, including meta-analysis, of the study protocols. Plans for interactions with CC investigators in the statistical analysis of the data collected in each study. Plans for preparing and presenting the study data as described in the technical and statistical reports.

8. Documentation of direct access and control of data processing and computer facilities for this program.

9. Describe organizational plans for day-to-day management of the study. Describe plans for the interactions with the statistical staff and the physician. Describe the functions and the role of the physician for this project.

10. Plans for collaborating with other CC investigators to make the studies comparable and complementary and contribute to the goal of identifying optimal patient populations, retinoids, doses, dosing schedules, routes of administration, and outcome measures. Plans for the development of common definitions, standardization of common procedures, compatible data forms, and a data analysis plan.

Personnel: The offeror must demonstrate that the staff needed to execute Phase I are available at the time of contract award in order to expedite the completion of Phase I. The Clinical Coordinating Center shall maintain a staffing level to ensure that the study results are published during Phase III. This will involve interaction with the clinical investigators and will require the timely transmission of the final data to the CCC and coordination of meetings to expedite the submission and publication of manuscripts. Proposals must provide evidence that personnel with the following expertise are available.

11. The Principal Investigator with demonstrated leadership experience in large data management systems, in protocol development for large multi-center research studies, and interaction with clinical center investigators from multiple sites.

12. Experienced biostatistical, statistical and medical investigators who have previous collaborative experience in the development of a study protocol and manual of operations, and monitoring data collection from multiple clinical sites to ensure that data are reviewed for completeness and that quality control is maintained prior to processing, and in conducting proper statistical analyses of the data for each study and for the program. Experience in meta-analysis methodology to analyze data across studies.

13. Regular commitment of a physician(s) with strong medical and scientific knowledge and experience in care and treatment of patients with emphysema for a minimum of 8 hours per week.

14. Offerors shall describe the experience of the auxiliary personnel including programmer, data manager, and data coordinator.

Facilities: Offerors must provide evidence that the facilities necessary to carry out this research program are available.

15. Offerors shall describe the office space that will be used for staff, including the physician. Describe the facilities available for filing, and data processing of records on patients enrolled in the study, including methods to insure safety and confidentiality of all records.

16. Describe computer facilities available for data storage, data processing and statistical analysis. If the technical approach proposed calls for a distributed data entry system for data collection and transmission, describe the computer facilities available for this purpose.

17. Describe facilities to assure production of patient forms, protocol, manual of operations, periodic reports and scientific reports and publications.

18. Describe major items of equipment that will be available to fulfill the requirements of the study. Indicate if any of the facilities that will be used on this project were purchased with Government funds.

e. Committees:

The following committees relate to the collaborative program and its activities.

The **Steering Committee** will be composed of the Principal Investigator from each of the Clinical Centers, the Principal Investigator from the Clinical Coordinating Center, and the NHLBI Project Officer. Offerors should not propose Committee members. The Committee will be chaired by an individual selected by NHLBI. The first charge of the Steering Committee will be to develop common study definitions, consider common outcome measures, standardize common procedures, common reporting formats, the manual of operations and the complementary aspects of the protocols.

The **Data and Safety Monitoring Board (DSMB)** will be established by the NHLBI to review the study protocols and monitor patient safety, study progress, data management and analysis, data outcomes and will advise NHLBI when changes should be made to the studies. It will meet in Phase I to review and recommend approval/disapproval of the study protocols to the NHLBI. During Phase II, it will meet twice per year to review study performance and study results and will evaluate the study procedures for beneficial and adverse effects. During Phase III, the DSMB will review papers resulting from the studies.

Other subcommittees may be established by the Steering Committee as needed (e.g., Mortality and Morbidity classification). It is anticipated that a **Publications and Presentations Committee** will be established for this program. The membership of the committee is expected to include representatives from the Clinical Centers, the Clinical Coordinating Center and the NHLBI. The committee will review proposed publications based on policies and procedures established by the Steering Committee. It is expected that criteria will include patient confidentiality issues and the timely publication of study results.

SECTION M—EVALUATION FACTORS FOR AWARD WITH TECHNICAL EVALUATION CRITERIA

The technical proposal will receive paramount consideration in the selection of contractors for this acquisition. The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully, based on responsiveness to the RFP and the thoroughness and feasibility of the technical approach taken. In the event that the technical evaluation reveals that two or more offerors are approximately equal in technical ability, then the cost of offerors may become a significant factor in determining award. In any event, the Government reserves the right to make an award to the best advantage of the Government, cost, and other factors considered.

Award of this RFP will be made only to offerors located in the United States of America. Proposals from offerors outside the United States will not be considered for award.

Proposals, included in the competitive range, will be reviewed to determine the extent to which the offeror identified specific Small Disadvantaged Business (SDB) concerns and the extent of commitment to use these SDB concerns in the performance of the contract. The extent of this participation may be discussed with those offerors whose proposals are included in the competitive range. See SPECIAL REQUIREMENTS, item d. on page 17.

Proposals submitted in response to this solicitation will be reviewed by a peer group of scientists under the auspices of the Review Branch, Division of Extramural Affairs, NHLBI, and subsequently by a review group within NHLBI. The following criteria and weight factors will be used by the initial peer review group in the evaluation of the proposals.

No.	Criterion:	Point
1.	Qualification and Experience of Professional Staff	**35**

The qualifications, leadership, research experience, commitment and competence of the professional, medical and technical staff pertinent to the program. In particular, a strongly integrated team with prior experience in collaborating in large scale multi-center clinical research studies, demonstrated experience in working with investigators from multiple sites, protocol development, expert in conducting research on and in the treatment of patients with emphysema, expert in statistics and biostatistics, including meta-analysis.

2. Scientific Merit of the Proposed Approach **35**

The plans for study coordination; data collection, data processing and transmission, statistical analysis, reporting, and quality assurance of data. Plans for monitoring of data for quality control, clinical center performance in enrollment of study participants and in collecting, processing, entering and transmitting the data. Plans for training staff in study procedures. Plans for completing analysis and publishing study results.

3. Understanding of the Scientific Issues of the Program **10**

Proposed plans for ensuring that the findings of each study are comparable and complementary and contribute to the goal of identifying optimal patient populations, retinoids, doses, dosing schedules, routes of administration, and outcome measures for a larger study, that would be conducted primarily in the USA, if indicated.

4. Facilities **20**

The administrative structure and the institutional support provided. Facilities and equipment including technical hardware and software necessary to carry out this program. Documentation of the facilities including the means of assuring quality control of data, data entry, confidentiality of data, and plans for day-to-day coordination.

Total: 100