DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

January 17, 1972

Request for Proposal RFP NHLI-72-22

Control of Lethal Arrhythmias Associated
With Coronary Heart Disease

Experimental Interventions and Studies Fundamental Thereto

The Myocardial Infarction Program of the National Heart and Lung Institute is soliciting proposals which will investigate the physiology and develop new preventive and therapeutic methods for the control of lethal arrhythmias associated with coronary heart disease, particularly those associated with ischemia and scarring. This solicitation encompasses both non-clinical and clinical studies. The non-clinical studies should focus upon studies of fundamental processes and interventions which may ultimately lead to clinically applicable techniques and investigations. Clinical studies should represent those approaches which are particularly promising and which are best conducted in the clinical setting.

The following topics are covered in the subsequent pages:

As described herein on Page 10, the Program Office will respond to inquiries.

Prospective applicants should indicate their intention to submit a proposal by a one paragraph letter to be received by the undersigned by February 18, 1972. This letter should very briefly describe the proposed study to permit optimal selection of the review committee; it is not a part of the proposal and will in no way influence the eventual selection.

Twenty copies of your proposal must be received by the Myocardial Infarction Branch, Building 31, Room 1B-55, National Heart and Lung Institute, 9000 Wisconsin Avenue, Bethesda, Md. 20014, by 5 p.m. EST, March 17, 1972.

Peter L. Frommer

Peter L. Frommer, M.D.
Chief, Myocardial Infarction Branch
National Heart and Lung Institute

PART I: BACKGROUND INFORMATION AND REQUIREMENTS

A. The Myocardial Infarction Program

The Myocardial Infarction Program of the National Heart and Lung Institute has the responsibility for the design and administration of a national research program leading to the reduction of death and disability from heart attack and sudden cardiac death. The Program is fostering the development of new knowledge and the translation of results into methods which will have wide clinical application.

The Program is structured with planned areas for support. It includes clinical and fundamental research directly related to the problem of myocardial infarction and sudden cardiac death. Because it is a program in which the various elements have relevance to one another and may depend upon each other, free communication is expected between the participants. The Program Office has direct interest in the scientific experience and results of each project as well as in its operational aspects. Goals must be clearly defined. The need for flexibility in research approach and operations is recognized, and modifications which are mutually agreed upon can be implemented.

The most widely known part of the Myocardial Infarction Program is a group of nine Myocardial Infarction Research Units which focus multi-disciplinary research efforts upon the hospitalized patient and upon relevant fundamental problems. More recently, programs have been undertaken on sudden cardiac death and the pre-hospital phase of myocardial infarction, fundamental studies on the protection of ischemic myocardium, and on the development of methods for quantifying the size of ischemic or infarcted myocardium suitable for use in man. In the past, the Program has supported the development of more satisfactory animal models of myocardial infarction for laboratory purposes. Several additional topics are under study for future support.

B. Control of Lethal Arrhythmias Associated with Coronary Heart Disease - Experimental Interventions and Studies Fundamental Thereto

1. Background

Fatal arrhythmias represent the leading immediate cause of death in the United States. Approximately 500,000 deaths per year can be directly attributed to lethal disorders of heart rhythm. Many, if not the majority, of these arrhythmias, which are now 100% fatal, are associated with severe but not otherwise lethal or incapacitating coronary atherosclerosis. More effective rhythm control could decrease the high mortality and morbidity now associated with coronary artery atherosclerosis.

The physiologic basis of fatal arrhythmias associated with coronary heart disease is imperfectly and incompletely understood. Further, the mechanism of action of drugs used in the management of these arrhythmias is even less well defined.

Prevention of lethal arrhythmias associated with coronary heart disease has depended primarily on suppression of precipitating abnormal heart beats with depressing agents such as lidocaine, quinidine and procainamide. This approach, although successful in many cases, has not been beneficial in certain "resistant" arrhythmias and in long term management where either route of administration, need for multiple daily doses or unfavorable toxic/therapeutic ratio has prevented adequate protection. Since present therapy is imperfect, improved basic knowledge has an excellent chance of improving management.

2. Goals and Scope

Proposals are being solicited for research which will investigate the physiology and develop new preventive and therapeutic methods for the control of lethal arrhythmias associated with coronary heart disease, particularly those associated with ischemia and scarring. This solicitation encompasses both non-clinical and clinical studies. The non-clinical studies should focus upon fundamental processes and interventions which may ultimately lead to clinically applicable techniques and investigations. Clinical studies should represent those approaches which are particularly promising and which are best conducted in the clinical setting.

The emphasis of proposals should preferably be upon the underlying mechanisms, prevention and therapy of terminal arrhythmias associated with coronary heart disease, rather than a focus on "premonitory" arrhythmias. Areas of particular interest include the relationship between lethal cardiac arrhythmias and neurohumoral mediators, the autonomic nervous system, local biochemical or electrolyte alterations, and/or hemodynamics.

Investigation in response to this solicitation should be directly related to the lethal arrhythmias associated with coronary heart disease. The goals are to 1) further the understanding of the basic pathophysiologic processes; 2) elucidate the mechanisms of the therapeutic interventions which are used in their control; and 3) develop new and better methods for their prevention and treatment.

It is recognized that this solicitation is likely to elicit responses with a considerable spectrum of activity and cost. Proposers should be aware that tentatively a total of $500,000 has been budgeted for the first year's cost of the contracts to be funded under this solicitation and that as an order of magnitude, four to ten contracts might be let. However, it is emphasized that both the allocation of funds and the number of contracts are estimates and may vary considerably; indeed, as indicated elsewhere in this solicitation, the Government reserves the right to reject any or all proposals.

3. Funding

Funding will be by contracts; the cost-reimbursement type of contract has found widest acceptance in the Myocardial Infarction Program in the past. Contracts probably will not be written for periods longer than one year. It is recognized that the research effort being sought will require longer period for its successful execution. Accordingly the acceptance of a research proposal would represent not a contractual obligation for renewal beyond the initial period, but the recognition that a program of longer duration is necessary for the successful completion of the task. Annual negotiations for renewals and extension are necessary.

Although this contract requirement is included and provided for in a financial plan for Fiscal Year 1972, award of a contract pursuant to this Request for Proposal is contingent upon ultimate receipt of appropriated funds. Offerors may therefore be requested to extend acceptance periods following receipt of proposals to the extent necessary to permit award when funds become available.

4. Further Information

The subsequent sections of this announcement include important additional information about the scientific, administrative, and legal requirements of the proposals and about the Program and its operation. The General Provisions (Negotiated-Cost-Reimbursement Contract, HEW-315), which discuss general contract requirements with non-profit institutions, and the General Provisions (Negotiated Cost-Plus-Fixed-Fee Contract, HEW-316), which apply to other institutions, may be obtained from this office.

Part II: INSTRUCTIONS TO OFFERORS

A. Method and Criteria for Review of Proposals

Proposals will undergo dual review. It may be necessary to conduct site visits or to have proposers meet with reviewers. Such arrangements would be made after the applications are received.

The factors considered in evaluating each proposal include:

1. The relevance and adherence of the proposal to the goals and scope of this request for proposal as described in Part I.B.2.

2. The scientific merit of the proposal - particularly the importance of the questions being proposed and the likelihood of obtaining answers in a reasonable period of time.

3. The research experience and competence of the investigators and the time they will devote to the program.

4. If pertinent, the availability of patients for study.

5. The adequacy of facilities and resources for the proposed program.

6. If there are multiple projects, their integration into an effective program and the relation of specific projects to other relevant programs of the proposer or in the proposer's community (this criterion may not be relevant to all proposals).

7. The organizational and administrative structure of the proposed program.

8. The evidence of institutional commitment to the program.

9. The cost of the proposed program.

B. Proposal Content, Format, and Instructions

The reviewers will want an introductory summary to provide a quick overview of the program and resources so that their study of the detailed proposal will be with a perspective of the total proposed program. The proposal must be prepared in sufficient detail that an expert in that area can assess its merits.

Proposals must be typed, preferably single spaced, on paper no larger than 8-1/2" x 11".

Proposals should be fastened within a folder; any unbound material should be labeled, folded, and inserted into envelopes bound to the proposal. Accurate indexing and pagination are necessary; tabbed indices may be of value.

Twenty legible copies of the proposal must be submitted.

For prompt acknowledgement of receipt of proposals, please include a self-addressed stamped card or letter stating "Proposal submitted by . . . . . in response to RFP NHLI-72-22 has been received."

The following sequence and format must be followed:

(These instructions are written for the general case of a "program" containing more than one "project" involving research or development in a clinical setting. Accordingly, some items may not be pertinent to a particular proposal. Also, the detail with which each item should be covered will vary according to the individual proposal.)

A) Cover

The name of the proposing institution and the RFP number and title should appear on the cover.
The copy bearing original signatures should be so identified on its cover.
The 20 copies should be numbered consecutively 1 through 20.
The following legend should appear on the cover:
"For Official Use Only. Information contained in this proposal is not to be revealed to any person not authorized by the National Heart and Lung Institute to review it."

B) Title Page-Summary Data Sheet

The Proposal Summary Data Sheet appearing as the last page of this solicitation must be completed in full and will serve as a title page.

C) Table of Contents

Provide sufficient detail that important elements of the total proposal, specific curriculum vitae, etc., can be located readily.

D) Introductory Summary

This is a brief summary outlining the proposed program goals, methods, facilities, personnel, and other material which will aid reviewers by providing a perspective for studying the detailed proposal.

E) Research Proposals

This section should provide the information which clearly defines the program goals, the information from which the likelihood of achieving these goals can be assessed, and the information from which the significance of the proposed program can be judged in the context of the goals of this solicitation. Accordingly, the working hypotheses, the methods of procedure, the size and scope of the undertaking, the anticipated problems, the expected results, and the limitations of the expected results should be clearly described. The proposal should clarify what is to be done in contrast to what is known or what is ongoing. Reasonably well known methods which are state of the art should be described only briefly; new techniques should be described fully. Illustrations which are of assistance should be included. The significance of the proposed project should be discussed, particularly in the context of the goals of this request for proposals, as well as its significance in any broader context. The experience of the applicant in the field of the proposal and in related fields should be reviewed. The relevant present knowledge and state of the art should be summarized.

Each project must be described in sufficient detail that an expert in that field can assess its merits. Each project should be described in the following format:

1. Title.
2. Project leader.
3. Other investigators.
4. Overall goals.
5. Specific short-term goals and milestones and dates for their attainment.
6. Methods of Procedure (including both scientific and operational aspects).
7. Significance (particularly in the context of the solicitation).
8. Previous work by applicant (in this and related fields).
9. Previous work by others (a concise summary, including pertinent literature references).

The technical proposal will be reviewed by scientists from the relevant disciplines who have a familiarity with the various aspects of the areas to be covered, and the total proposal -- particularly the summary and technical sections -- should be written with this in mind. When

necessary, more extensive background material or detailed documentation should be included in a clearly referenced appendix.

F) Statement of Work

This section of the proposal should define the total scope of the proposed program, including a listing of the tasks to be performed with a schedule that relates the tasks to one another. From the body of the proposal -- particularly Section E above -- it should be evident how these goals will be achieved, which projects relate to which tasks, and the estimated level of effort necessary to accomplish each task.

G) Facilities and Resources

Describe existing facilities and resources which will be used for the program.
Describe any new facilities which must be made available for the program and justify them in terms of research needs.
If not already apparent, describe the relationship of these facilities and resources to the proposed research projects.

H) Equipment

Describe the existing major equipment which will be available for use in the program.
Describe any major equipment which must be made available to the program and justify in terms of research need.

I) Patient Availability

If pertinent, describe the availability of patients for the proposed research, the characteristics of the patient population, and the cooperation of physicians and others in the community whose involvement might be essential.

J) Organization and Administration

Describe the administrative relationships of the proposed projects within the sponsoring institute:

1) which department or office will have administrative responsibility for the program

2) how the program will relate to other departments or research groups in the institution or community and what organizational or other means will be used to encourage participation of scientists with relevant interests in the program

3) who would be responsible for the appointment of a new project director should the incumbent leave.

Describe the organization of the program, including the names of personnel who have been selected.
Show lines of responsibility for administrative matters, planning and conduct of research, and patient care.

K) Support for Related Work

Briefly describe all work being carried out by your organization which is related to the work covered by this proposal, and indicate the sources of support (both current and applied for) for such related work. If grants or contracts support such work, specify how the work under this proposal will relate to and differ from such supported work. Sufficient information must be presented to enable the Program Office to ensure that funds asked for and awarded under this proposal are used only for purposes specified in contracts awarded under this RFP.

L) Additional Institutional Resources

Describe briefly any programs or resources heretofore not discussed with which the proposed program may interact.

M) Budget

This portion of the proposal should contain all information relative to costs and pricing, including an accurate, current and complete cost estimate for all work and materials proposed. Cost estimates for any subcontracts should be included. It should be noted that no costs of a contractor's independent research and development work are allowable.

The proposed budget must appear in the following format:

1) Summary budget
2) Detailed budget for the total proposal
3) Detailed budget for each project, if applicable
4) A tentative summary budget for subsequent years, if applicable

(The detailed budget for the total proposal should integrate the individual project budgets by combining identical items and by listing similar items consecutively.)

Each budget should utilize the thirteen subdivisions indicated below:

1) Scientist and Senior Personnel
2) Other Personnel
3) Equipment Purchase
4) Equipment Rental
5) Supplies

6) Hospitalization Costs
7) Outpatient Costs
8) Travel (domestic only)
9) Alterations and Renovations
10) Publication Costs
11) Other Direct Costs -- including subcontracts
12) Overhead (% of item(s) _____above)
13) Fixed Fee
14) Total Cost to Government

Personnel sections (in both the integrated and individual project budgets) should utilize the following format:

Position	Name	Indicate % Effort, Hrs/Wk or Total Hrs	Cost	Fringe Benefits	Total

For each scientist or senior position, indicate the person proposed or indicate "unfilled." For other positions, indicate "on hand" or "unfilled."

All professional personnel working on this program should be listed and their time commitment indicated, whether or not any portion of their salary is to be charged to this program.

All substantial budgetary items must be justified as to need and (where appropriate) as to basis for estimate, either by specific footnote to the budget or elsewhere within the proposal.

N) Required Certification

This section should include all statements or certifications required under Part III of this RFP except the final page (which becomes the Title Page, B above).

O) Curricula Vitae and Bibliographies

For each investigator a curriculum vitae and bibliography should be included; these may be brief and selective (if selective, so indicate). If these are in any order other than alphabetical, their sequence should appear in the table of contents.

P) Appendices

C. General Instructions

Inquiries

If questions arise which do not seem to be answered adequately in this

request for proposals or in the General Provisions, inquiries may be directed to the Program Office by telephone or mail.

Letter of Intent

Prospective applicants are asked to indicate their intent to submit a proposal by a one paragraph letter very briefly describing the study to be proposed. This material should be submitted to the address and by the time specified in the covering letter. This does not constitute a portion of the formal proposal.

Receipt and Review of Proposals

Twenty copies of proposals should be submitted in time to arrive in Room 1B-55, Building 31, National Institutes of Health, Bethesda, Maryland 20014, not later than the time specified in the covering letter of this RFP. Telegraphic bids will not be accepted. The Government reserves the right to consider proposals or modifications thereof received after the date indicated but before award is made, should such action be in the best interest of the Government.

It may be necessary to conduct site visits or to have the proposers meet with the review committee. Such arrangements would be made after the applications are received.

Negotiation of Contracts

After the review and preliminary selection, the Program Office may invite certain proposers for discussion of possible modification of the proposed research program. Subsequently, formal negotiations may be undertaken leading to the award of contracts. However, the Government reserves the right to accept proposals as submitted, without negotiation.

Acceptance of Proposals

The Program Office reserves the right to reject any and all proposals. It also reserves the right to select proposals for final negotiation without prior discussions with the proposers. Therefore, proposals should be submitted in terms that are most favorable from a price and technical standpoint.

Contracting Authority

A duly authorized Government contracting officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with this announcement. This request for proposals does not commit the Government to award a contract or to pay any direct costs incurred in the preparation of a response to this request or to procure or contract for this work.

Announcement of Award

All offerors will be notified of their selection or non-selection as soon as possible after final decisions are made. Formal notification of non-selection cannot be made until contracts have been awarded; the review and award process takes approximately four months from the date of receipt of proposals.

Proprietary Information

Proprietary information appearing in your proposal should be clearly identified as such. Non-Government personnel may be used to assist in the evaluation of proposals and the submission of your proposal will be regarded as your consent to making the identified information available to such non-Government personnel for this purpose. All information will, of course, be held in strictest confidence.

Reporting Requirements

Frequent personal communication between the contractor's scientists and the Program Office is anticipated. One month after award of contract, a program plan presenting a detailed description of activities for the entire contractual period planned with a time oriented sequence will be submitted for approval. Informal quarterly progress reports must be submitted briefly describing the work performed during the quarter, a summary of financial obligations incurred, problems encountered, and anticipated activities. A comprehensive annual report must be submitted which describes all of the activities and presents the results of the year's work.

Financial Capability

The offeror should indicate if he has the necessary financial capability, working capital, and other resources to perform the contract without assistance from any outside source. (If not, indicate the amount required and the anticipated source.)

Signature

The proposal must be signed by an official authorized to bind the offeror, and it shall contain a statement to the effect that the proposal is firm for a period of at least 120 days from the closing date of receipt thereof by the Government.

(This attachment - or a copy thereof - shall be executed by an official authorized to bind the offeror, detached and made a part of his business management proposal.)

Part III

Offeror's Representations, Certifications

and Acknowledgments

The offeror makes the following representations and certifications as part of his proposal (check or complete all appropriate boxes or blanks).

1. SMALL BUSINESS REPRESENTATION

He ( ) is, ( ) is not, a small business concern. If he is a small business concern and is not the manufacturer of the supplies to be furnished hereunder, he also represents that all such supplies ( ) will, ( ) will not, be manufactured or produced by a small business concern in the United States, its possessions, or Puerto Rico. If a small business concern, Contractor represents that he ( ) has, ( ) has not, previously been denied a Small Business Certificate of Competency by the Small Business Administration. (A small business concern for the purpose of Government Procurement is a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is contracting and can further qualify under the criteria concerning number of employees, average annual receipts, or other criteria, as prescribed by the Small Business Administration.) (See Code of Federal Regulations, Title 13, Part 121, as amended, which contains detailed definitions and related procedures.)

2. TYPE OF ORGANIZATION

He operates as an ( ) INDIVIDUAL, ( ) STATE OR LOCAL AGENCY, ( ) PARTNERSHIP, ( ) JOINT VENTURE, ( ) NONPROFIT, ( ) EDUCATIONAL INSTITUTION, ( ) CORPORATION organized and existing under the laws of the State of _____.

3. CONTINGENT FEE REPRESENTATION (Applicable only to proposals in which the aggregate amount involved exceeds $2,500.)

Offeror represents: (a) that he ( ) has, ( ) has not, employed or retained any company or person (other than a full-time bona fide employee working solely for the offeror) to solicit or secure this

contract, and (b) that he ( ) has, ( ) has not, paid or agreed to pay any company or person (other than a full-time bona fide employee working solely for the offeror) any fee, commission, percentage or brokerage fee, contingent upon or resulting from the award of this contract; and agrees to furnish information relating to (a) and (b) above as requested by the Contracting Officer. (Note: For interpretation of representation, including the term "bona fide employee," see Code of Federal Regulations, Title 41, Chapter I, Subpart 1-1.5).

4. EQUAL OPPORTUNITY CERTIFICATION

a. Have you participated in any contractual agreement which contained the Equal Employment Opportunity Clause prescribed in Executive Order 10925, 11114, or 11246?

( ) Yes. ( ) No.

b. Were you required pursuant to the Rules and Regulations of Equal Employment Opportunity (41 CFR 60-1) to file a compliance report as the result of such contractual agreement?

( ) Yes. ( ) No. If "Yes," answer question (c).

c. Did you file the necessary compliance report in accordance with the instructions contained on the appropriate report form -- SF-40, SF-41, or EEO-1 (SF-100)?

( ) Yes. ( ) No. If "Yes," answer question (d).

d. Name of agency requiring report _____

_____

e. When was report filed? _____

f. Has any action been required of you to improve your compliance posture?

( ) Yes. ( ) No.

g. Name and address of Government "Compliance Agency," if known:

_____

_____

h. What is your current employment? _____

i. Have you prepared a written affirmative action compliance program?

( ) Yes. ( ) No. If "No," reason for this is:

( ) Offeror is an agency or instrumentality of state or local government.

( ) Offeror employs less than 50 persons.

( ) Offeror has not been awarded a Federal contract or subcontract of $50,000 or more since July 1, 1968.

j. DATA ON SUBCONTRACTORS (Use supplementary sheets where required.)

Name of Subcontractor and Address	(1)	(2)	(3)
	( )Yes( )No	( )Yes( )No	( )Yes( )No
	( )Yes( )No	( )Yes( )No	( )Yes( )No

(1) Previously held contracts subject to E.O. 10925, 11114, and 11246
(2) Previously filed certificate of nonsegregated facilities
(3) Previously filed compliance report (SF-40, SF-41, or EEO-1)

5. CERTIFICATION OF INDEPENDENT PRICE DETERMINATION AND COMPLIANCE WITH EXECUTIVE ORDER 11615

a. By submission of this bid or proposal, each bidder or offeror certifies and in the case of a joint bid or proposal, each party thereto, certifies as to its own organization, that in connection with this procurement:

(1) the prices in this bid or proposal have been arrived at independently, without consultation, communications, or agreement, for the purpose of restricting competition, as to any matter relating to such prices with any other bidder or offeror or with any competition.

(2) unless otherwise required by law, the prices which have been quoted in this bid or proposal have not been knowingly disclosed by the bidder or offeror and will not knowingly be disclosed by the bidder or offeror prior to opening, in ths case of a bid, or prior to award, in the case of a proposal directly or indirectly to any other bidder or offeror or to any competitor; and

(3) no attempt has been made or will be made by the bidder or offeror to induce any other person or firm to submit or not to submit a bid or proposal for the purpose of restricting competition.

b. Each person signing this bid or proposal certifies that:

(1) he is the person in the bidder's or offeror's organization responsible within that organization for the decision as to the prices being bid or offered herein and that he has not participated, and will not participate, in any action contrary to (a) (1) through (a) (3) above; or

(2) (i) he is not the person in the bidder's or offeror's organization responsible within that organization for the decision as to the prices being bid or offered herein but that he has been authorized in writing to act as agent for the persons responsible for such decision in certifying that such persons have not participated, and will not participate, in any action contrary to (a) (1) through (a) (3) above, and as their agent does hereby so certify; and (ii) he has not participated, and will not participate, in any action contrary to (a) (1) through (a) (3) above.

c. This certification is not applicable to a foreign bidder or offeror submitting a bid or proposal for a contract which requires performance or delivery outside the United States, its possessions, and Puerto Rico.

d. A bid or proposal will not be considered for award where (a) (1), (a) (3), or (b) above has been deleted or modified. Where (a) (2) above has been deleted or modified, the bid or proposal will not be considered for award unless the bidder or offeror furnishes with the bid or proposal a signed statement which sets forth in detail the circumstances of the disclosure and the head of the agency, or his designee, determines that such disclosure was not made for the purpose of restricting competition.

e. By submission of this bid (offer) bidder (offeror) certifies that he is in compliance and will continue to comply with the requirements of Executive Order 11615, August 15, 1971, for the duration thereof and further certifies that the prices bid (offered) herein conform to the requirements of Executive Order 11615 or shall be reduced accordingly at the time of any billings that are made during the effective period of the Executive order.

6. CERTIFICATION OF NONSEGREGATED FACILITIES

(Applicable to contracts, subcontracts, and agreements with applicants who are themselves performing federally assisted contracts, exceeding $10,000.00 which are not exempt from the provisions of the Equal Opportunity Clause.)

By the submission of this bid, the bidder, offeror, applicant, or subcontractor certifies that he does not maintain or provide for his

employees any segregated facilities at any of his establishments, and that he does not permit his employees to perform their services at any location, under his control, where segregated facilities are maintained. He certifies further that he will not maintain or provide for his employees any segregated facilities at any of his establishments, and that he will not permit his employees to perform their services at any location, under his control, where segregated facilities are maintained. The bidder, offeror, applicant, or subcontractor agrees that a breach of this certification is a violation of the Equal Opportunity clause of this contract. As used in this certification, the term "segregated facilities" 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, transportation and housing facilities provided for employees which 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. He further agrees that (except where he has obtained identical certifications from proposed subcontractors for specific time periods) he will obtain identical certification from proposed subcontractors prior to the award of subcontracts exceeding $10,000.00 which are not exempt from the provisions of the Equal Opportunity clause; that he will retain such certifications in his files; and that he will forward the following notice to such proposed subcontractors (except where proposed subcontractors have submitted identical certifications for specific time periods).

7. NOTICE TO PROSPECTIVE SUBCONTRACTORS OF REQUIREMENT FOR CERTIFICATION OF NONSEGREGATED FACILITIES

A certification of Nonsegregated Facilities, as required by the May 9, 1967, order (32 F.R. 7439, May 19, 1967) on Elimination of Segregated Facilities, by the Secretary of Labor must be submitted prior to the award of a subcontract exceeding $10,000.00 which is not exempt from the provisions of the Equal Opportunity clause. The certification may be submitted either for each subcontract or 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.

8. DUPLICATION OF COST

The Contractor represents and certifies that any charges contemplated and included in his estimate of cost for performance are not duplicative of any charges against any other Government contract, subcontract, or other Government source.

9. INVESTIGATIONS INVOLVING HUMAN SUBJECTS

Concern over the rights and welfare of the human being as a subject of research has led to Public Health Service policy to help assure his protection. Any activity which includes such research must provide for the individual's safety, health, and welfare. His rights, including his rights of privacy, must not be infringed. His participation must be voluntary. The direct or potential benefits of the research must outweigh the inherent risks to the individual. This policy applies to all research activities supported through grants, awards, or contracts by the National Institutes of Health.

This institute must provide written assurance to the Public Health Service that it will abide by this policy for all research involving human subjects supported by the Public Health Service. This assurance shall consist of a written statement of compliance with the requirements regarding initial and continuing review of research involving human subjects and a description of the institution's review committee structure, its review procedures, and the facilities and personnel available to protect the health and safety of human subjects. In addition to providing the assurance, the institution must also certify to the Public Health Service for each proposal involving human subjects that its committee has reviewed and approved the proposed research before an award may be made.

The booklet "Protection of the Individual as a Research Subject" presents the Public Health Service policy on human ivestigation and specifies the requirements for written assurance of institutional compliance with this policy and for certification of individual contract proposals.

10. NONDISCRIMINATION BECAUSE OF AGE

It is the policy of the Executive Branch of the Government that (a) contractors and subcontractors engaged in the performance of Federal contracts shall not, in connection with the employment, advancement or discharge of employees, or in connection with the terms, conditions or privileges of their employment, discriminate against persons because of their age, except upon the basis of a bona fide occupational qualification, retirement plan or statutory requirement; and, (b) that contractors and subcontractors, or persons acting on their behalf, shall not specify, in solicitations or advertisements for employees to work on Government contracts, a maximum age limit for such employment unless the specified maximum age limit is based upon a bona fide occupational qualification, retirement plan or statutory requirement.

11. The proposer should indicate that General Provisions - Negotiated Cost-Reimbursement Contract (HEW-315) are acceptable ( ) or not acceptable ( ), or General Provisions - Negotiated Cost-Plus-Fixed Fee Contract (HEW-316) are acceptable ( ) or not acceptable ( ) because:

To be completed by offeror:

_____ _____

Name of Offeror Date

_____ _____

Signature Title

NOTICE OF REQUIREMENT FOR CERTIFICATION OF NONSEGREGATED FACILITIES

Bidders and offerors are cautioned as follows: By signing this bid or offer, the bidder or offeror will be deemed to have signed and agreed to the provisions of the "Certification of Nonsegregated Facilities" in this solicitation. The certification provides that the bidder or offeror does not maintain or provide for his employees facilities which are segregated on a basis of race, creed, color or national origin, whether such facilities are segregated by directive or on a de facto basis. The certification also provides that they will not maintain such segregated facilities. Failure of a bidder or offeror to agree to the Certification of Nonsegregated Facilities will render his bid or offer nonresponsive to the terms of solicitations involving awards of contracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity clause.

NOTE: Offerors must set forth full, accurate and complete information as required by the solicitation (including attachments). The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

PROPOSAL SUMMARY DATA SHEET

1. NHLI-RFP No. _____
2. Name of offeror: _____
3. Total estimated time required to complete project: _____
4. Total estimated costs:

First year	_____
Second year	_____
Third year	_____
Fourth year	_____
Fifth year	_____

5. Type of contract proposed:

Cost-Reimbursement	_____	Cost-Plus-Fixed-Fee	_____
Cost-Sharing	_____	Fixed-Price	_____
Other	_____		

6. Principal Investigator(s) and Senior Scientists:

Name	Tel. No.	% of Time or Hours Weekly	Soc. Sec. No.

Mailing address of first named _____

7. Individual(s) authorized to negotiate:

Name	Title	Tel. No.

Mailing address of first named _____

8. Individual(s) authorized to execute and sign contracts:

Name	Title	Tel. No.

9. Subcontractor Information: (Furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)