PUBLIC INFORMATION AND COMMUNICATION SERVICES (PICS)

NIH-TASK ORDER

RFTOP# 169
TITLE: Inventory and Evaluation of Clinical Research Networks

PART I - REQUEST FOR TASK ORDER (TO) PROPOSALS

A. Point of Contact Name: Robert Best - Phone: (301) 435-0330 Fax: (301) 480-3330

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If you have any questions regarding this RFTOP, please contact the Contracting Officer at rb45o@nih.gov or submit your questions via facsimile. Collect calls will not be accepted. The submission of the proposals using facsimile or electronic mail is not authorized. If Mr. Best is not available, please contact John Taylor, at taylorjc@nhlbi.nih.gov , telephone 301-435-0345.

B. PROPOSED PERIOD OF PERFORMANCE: Eighteen months from the date of award. The target award date is September 30, 2004.

C. PRICING METHOD: Cost-Plus-a-Fixed-Fee. The Government anticipates awarding one contract as a result of this RFTOP. We estimate approximately 36 FTEs will be needed in the first twelve months and 22 FTEs will be needed in the last 6 months.

D. PROPOSAL INSTRUCTIONS: The response to this RFTOP must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." An original and twenty (20) copies of the technical proposal, an original and ten (10) copies of the business proposal, and a computer disk using the Excel based NIH spreadsheet (see below) must be submitted with the proposals, to the address listed above.

Page and Formatting Limitations

The Technical Plan (objectives, approach, methods and procedures, and schedule) of the Technical Proposal shall not exceed *30* single-sided pages or *15* double-sided pages. This page limitation does not apply to the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, other support, cost information, and literature cited. Appendices shall be limited to *100* single-sided pages or *50* double-sided pages.

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

Official Signature

The offeror must identify a senior company official on the cover page of the proposals, including a name, telephone number, facsimile number, e-mail address, the name and address of the company, the title of the project, the task order proposal number, and the date of submission. The official's signature will be needed on the cover page as well.

Automated Information System Security Plan

Offerors will need to consider system security. Attachment 3 is a provision that is applicable to this solicitation; the NHLBI Information System Security Officer and the Project Officer will be making a determination shortly on the sensitivity and security level designations and this will be conveyed to offerors in an amendment:

Cost Proposal

Please use the instructions found at http://ocm.od.nih.gov/contracts/rfps/BUSCOST.HTM , including the electronic spreadsheet link found there. Note that there is no Section L associated with this task order solicitation; applicable information from a typical Section L is included below.

Additional Technical Proposal Instructions

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(a) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

(b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Proposals based upon the offeror's best alternative schedule, will be accepted for consideration provided the requested schedule is addressed as well.

(c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs.

Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON OTHER PROJECTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Senior Personnel

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement.

Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(d) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria, attached.

(e) **Additional Technical Proposal Information**

Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. The technical evaluation is conducted

in accordance with the weighted technical evaluation criteria. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(f) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

1) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

2) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

3) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

4) Other factors you feel are important and support your proposed research.

5) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

E. RESPONSE DUE DATE: **April 2, 2004, at 4:00 PM Eastern time.**
F. TASK DESCRIPTION: See Statement of Work, Attachment 1.
G. EVALUATION CRITERIA: See Evaluation Criteria, Attachment 2.
H. AISSP: See Attachment 3

(END OF DOCUMENT)

CLINICAL RESEARCH INVENTORY: **STATEMENT OF WORK**

I. General Description of the Required Objectives and Desired Results

The overall goal of this task order is to assess best practices in clinical research networks by conducting an inventory of existing networks to examine characteristics relating to: focus (such as types and volume of studies), organizational and management structure, definitions and descriptions of the network structure and goals, evaluation of network performance, informatics infrastructure, training procedures, and other important characteristics related to the success of clinical networks.

The inventory should include public and private networks, those engaged in international research and those focused on research with underserved populations. The inventory should include those entities focused on defined populations; those organized by locus of care, different types of health care

providers such as nurse practitioners or psychologists; and disease-specific specialty groups. Also included should be factors that promote or are barriers to successful interactions and expansion or broadening of research scope. It is recognized that it is impractical to make an exhaustive inventory of all extant clinical research networks. However, it is important that the inventory created under this task be as complete as possible in ascertaining and cataloging the different types of existing networks, and that it explore current capabilities and alternative solutions to clinical research barriers present in the biomedical community. As NIH intends to make the data broadly available to researchers for use in selecting networks for clinical studies, the information captured in this inventory will be made available in an electronic inventory database.

II. Background Information

This initiative is one component of the NIH roadmap activity to re-engineer clinical research, the goal of which is to enhance the efficiency and productivity of the clinical research enterprise by promoting clinical research networks to conduct rapidly high quality clinical studies, including clinical trials, where multiple research questions can be addressed. Clinical research networks will work with aligned groups to promote the rapid dissemination of these study results into clinical practice. The clinical research networks will provide an infrastructure for a National Clinical Research Associates Program and will utilize the tools and systems developed through a National Electronic Clinical Trials and Research (NECTAR) network (http://nihroadmap.nih.gov/grants/rm-04-23.htm). This inventory will help provide an empirical basis for various efforts under the NIH Roadmap to re-engineer the clinical research enterprise.

III. Detailed Description of Technical Requirements

The biomedical research community has developed a large number of organizational and technical strategies to form clinical research networks. The goal of this inventory is to identify and describe a wide variety of models and approaches used to create clinical research networks as well as other important operational aspects, such as their information technology systems, organizational structure, and training activities. For the purposes of this solicitation, **a clinical research network is defined as an organization of clinical field sites and investigators that conduct multiple research protocols, often concurrently. The organization of sites and investigators may be formal or informal as long as the network's collaborative accomplishments can be shown. A group of investigators that is brought together to conduct a single protocol and then disbanded, is not considered a network for the purposes of this solicitation.**

The specific objectives that will lead to this goal are divided into three broad categories with the expected time periods needed to accomplish them.

Note to offerors: Indicate in your proposal where any request for OMB Clearance will be needed. Include in your proposed time line the anticipated time needed to obtain OMB Clearance. Show what activities can continue while waiting for OMB Clearance and make appropriate adjustments in your proposed costs. Show what impact OMB Clearance will have on the time allotted for each Major Goal below.

First Major Goal: Development of Inventory and Database of Clinical Research Networks *(6 months)*.

1) Identification of diverse clinical research network models from academia, government, and industry to provide broad representation of major clinical network types, population samples, and study components; 2) Development of a format for the inventory and database for information which will be provided by the clinical networks in relation to focus, management, administrative and functional structure, governance, and informatics infrastructure supporting the network; 3) Collection and verification of inventory information from the largest practical number of clinical research networks for use in and distribution in a World Wide Web-accessible inventory electronic database*;* 4) Description of all activities related to training investigators within each network; 5) Review of the inventory to ensure that the database is complete and reflects a broad representation of the various types of clinical research networks.

Second Major Goal: Detailed Description of Existing Practices and Assessment of Best Practices *(12 months).*

Assessment and identification of best practices in not less than one third of the networks surveyed for dissemination and implementation to the broader clinical research enterprise. Key to this assessment will be evaluations of the efficiency and effectiveness of each type of network in delivering the objectives of its stated mission, as well as its extensibility, scalability, and capacity to interoperate with other networks. Each of these assessments will focus on two or more key components of a successful network such as the informatics infrastructure, the administration and management of the network, the training conducted by the network, or efforts to harmonize nomenclature, data standards, or data collection systems with national standards.
In these in-depth evaluations, the contractor should attempt to obtain diversity on the dimension of type of sub-speciality (e.g. family practice, internal medicine, mental health specialities, pediatrics). The contractor will evaluate each of the selected existing networks to determine what systems work best for specific types of research (e.g. clinical trials, observational epidemiology studies, outcomes research). These assessments will also examine activities in both the public and private sectors, identify the scope and goals of these efforts and assess whether any of the current activities are of sufficient quality and sufficiently developed to be adapted for use nationally. Overall, the in-depth assessments and data in the inventory will assist in the definition of the characteristics that promote, or serve as barriers to, successful clinical research interactivity, productivity, and expansion or broadening of research scope,

including training of investigators.

These evaluations will include the current national efforts to harmonize nomenclature, data standards and data collection systems (including both forms and use of data that are routinely collected electronically during the course of clinical care).

Third Major Goal: National Leadership Forum on the Results of Inventory and the Assessment Studies *(18 months)*.

The contractor will convene a National Leadership Forum to present the results of the inventory project including aspects related to: successful interactivity within and among networks, factors promoting expansion or broadening of research scope, measures of efficiency, and sharing, ownership of and access to data for clinical research.

IV. Specific Objectives:

A. Identify established clinical research networks supported or coordinated by academia, government, industry, other private sector groups, or other sources to ensure sufficient representation of major types and near-complete sampling of models potentially applicable to a broader clinical research enterprise**.**

Tasks and Subtasks: The contractor will be responsible for all activities related to identifying clinical research networks including, but not limited to:

1. Identify existing clinical research networks, defined as an organization of clinical field sites and investigators that conducts multiple research protocols, often with more than one protocol ongoing at a time. The organization of sites and investigators may be formal or informal as long as the network's collaborative accomplishments can be shown. The contractor will briefly characterize the networks on factors including, but not necessarily limited to:

a) Number and type of clinical sites (e.g. academic, office), description of the individual components;
b) List of concurrent protocols, including the name of each trial, the ClinicalTrials.gov unique identifier for the trial (if available), and average number of concurrent subjects under study protocols;
c) Disease(s) or condition(s) studied;
d) Date of establishment of network;
e) History of expansion of network from fewer to more sites or more diseases/conditions;
f) Source(s) of funding (academia, government, non-profit, for-profit, other);
g) Direct and indirect costs of the network and other resources used by the network to

accomplish its work;

h) Efficiency and effectiveness for identifying and developing clinical protocols, designing and implementing the studies under the infrastructure of a clinical research network.

2. Group existing networks by degrees of similarity to identify major types and models for in-depth study; submit proposed groupings for review by an NIH oversight group. Such grouping should be aimed at advancing the goals of the inventory (e.g. informatics approaches, data use categories, populations).

3. Identify networks through, at a minimum, review of federal sources such as NIH CRISP Database, AHRQ, FDA, CDC, Department of Defense, and VA; contact relevant professional organizations including medical specialities; consult with experts, and use other resources and techniques.

4. Propose 2-3 representative models of each major type**,** as well as each model deemed unique, for in-depth study; submit to an NIH oversight group for review and approval.

5. Deliverables expected for Specific Objective A.

a) A preliminary list of existing clinical research networks (name of network and institutions involved) within 1 month of award.
b) Brief characterization of listed networks, and propose groupings and models within 3 months of award.
c) A list of proposed representative and models for in-depth study within 5 months of award. This list should be shared with the NIH oversight committee during the process.

B. Characterize in detail the selected networks in relation to focus, management and governance, informatics, and training.

Tasks and Subtasks: The contractor will be responsible for all activities related to characterizing clinical research networks in detail including, but not limited to:

1. Focus (e.g., types and volume of studies, diseases or conditions studied)

2. Management and governance
a) Protocol development and approval
b) Human subjects protections, maintenance of confidentiality, informed consent
c) Subject recruitment and retention
d) Study procedures
e) Quality control and standardization

f) Data management and system security
g) Data analysis and publication
h) Data sharing and dissemination
i) Network and committee structure
j) External oversight
k) Sponsor involvement
l) Leadership elements (e.g. experience of investigators, commitment)
m) Measures of productivity

3. Effectiveness in changing clinical practice based on evidence generated by the network (e.g. number of publications, numbers of trainees in the network that go on to academic careers).

4. Detailed description of the informatics infrastructure

a) System architecture for the information systems supporting the selected networks. The inventory should describe the system with respect OMB guidance's on federal information systems and/or accepted international standards such as ANSI/IEEE Std 1471-2000 "IEEE Recommended Practice for Architectural Description of Software-Intensive Systems 2000". The inventory should address the informatics characteristics of systems including their content, structure, and messaging strategies.

b) Software system components. Describe the use of commercial products and custom software developed for support of the selected networks. The inventory should catalog which elements are proprietary. For customized applications the inventory must describe the use of industry best practices in the development of the components. Of particular interest is the description of software components that facilitate knowledge discovery and knowledge management. For example,

i) integration of multiple data sources
ii) handling of noisy, missing, or irrelevant data
iii) data and knowledge representation
iv) use of information standards including standard vocabularies/ontologies
v) use of common data elements (CDEs) in the system
vi) process and outcome evaluation
vii) data system security
viii) data submission format

5. Description of training and the training infrastructure including but not limited to, kinds and amount of training and retraining provided to new and existing researchers, clinicians, study coordinators and data

managers.

a) Determine the number and types of physicians, other health professionals, study coordinators and staff; where they are based (community/hospital, academic health centers, etc); range of specialties, type of practice speciality, who participates in the selected clinical research networks, and provide valid data on training opportunities, recruiting, incentives, and outcomes of any formal and informal training activities and programs within the selected networks.

b) Provide an estimate of costs to train personnel needed for conducting studies under a network.

c) Describe the selected networks' training operations. For networks with substantial community participation (e.g. office based providers), capture the trial name and ClinicalTrials.gov unique identifier for the trial (if available), overall accrual and accrual from the community. Describe interactions with community/hospital-based physicians, e.g., recruitment, retention, productivity, incentives. Describe: 1) strengths and weaknesses of the training efforts of each network, 2) lessons learned, 3) strategies used to overcome barriers, 4) areas that could be improved or changed, 5) the efficiency and attractiveness of training within the network concept as compared to clinical training using other mechanisms, 6) benefits and drawbacks of training with community and academic physicians, 7) training that leads to individual team members obtaining certification.

6. Deliverables expected for Specific Objective B.

a) A detailed report highlighting the focus, management and governance approaches used in the selected networks (e.g. quality control, access, ownership, sharing policies, degree of use by other investigators, intellectual property issues, usage of limited samples, credentialing and prioritization of access to any samples, regulatory issues such as HIPAA) within 9 months of award.

b) A comprehensive overview and assessment report of the informatics infrastructure used in various representative networks. This should include the proposed systems architecture, development strategy, project management approach, and any novel informatics approaches and solutions to implement protocols to obtain high efficiency and productivity. The report will describe the procedures, methodologies, and definitions used, including full documentation for an electronic database. It will describe the process for designing, modeling and implementing an electronic database of the best network informatics practices for the inventory, using a well defined database model that will facilitate machine based interoperability with tools such as universal modeling language, strategies for maintaining and easily updating the internet based

inventory database, costs, and a means to evaluate its use within 9 months of award.

c) A detailed report of the kinds of training activities, outcomes, costs, barriers, effectiveness in changing clinical practice based on evidence generated by the network, and possible solutions to overcome training obstacles within 9 months of award.

C. Assess and identify best practices in selected networks including informatics and administration and management approaches used in existing clinical research networks, for potential dissemination and implementation in a broader clinical research enterprise.

Tasks and Subtasks: The contractor will be responsible for all activities related to identifying best practices in existing clinical research networks including, but not limited to:

1. Successful interactions within networks
    a) Factors promoting interactivity
    b) Factors impeding interactivity (barriers)
    c) Possible solutions to identified barriers

2. Successful interactions with other networks
    a) Factors promoting interactivity
    b) Factors impeding interactivity (barriers)
    c) Possible solutions to identified barriers

3. Factors promoting expansion or broadening of research scope
    a) Factors promoting expansion
    b) Factors impeding expansion (barriers)
    c) Possible solutions to identified barriers

4. Measures of efficiency
    a) Capacity to achieve economies of scale in personnel and funding
    b) Speed and efficiency of conducting multiple and simultaneous trials
    c) Ability to accommodate high volumes of subjects or numbers of concurrent protocols
    d) Ability to test hypotheses more quickly than other mechanisms supporting clinical trials
    e) Strengths, weaknesses and merits of different informatics platforms.

5. Deliverables expected for Specific Objective C.

    a) A list of factors promoting and impeding interactivity within networks and possible

solutions within 9 months of award.

b) A list of factors promoting and impeding interactivity with other networks and possible solutions within 10 months of award.

c) A list of factors promoting and impeding expansion or broadening of scope and possible solutions within 11 months of award.

d) A list and description of the characteristics that promote efficiency in the networks inventoried within 12 months of award.

D. Develop an electronic database of the inventory results for distribution in a World Wide Web accessible inventory database.

Tasks and Subtasks: The contractor will be responsible for all activities related to developing an electronic database including, but not limited to:

1. Defining the inventory structure using categories related to the following representative "Aggregate Data" Use Categories for the proposed database:

a) Observational Epidemiology Studies
b) Clinical Trials
c) Outcomes Research
d) Best Practice Modeling: clinical guidelines, expert systems
e) Efficient and Effective Care Delivery

2. Establishing a user friendly website for navigating and interrogating the database.

3. Obtaining input from users on limitations or gaps in the database and challenges to using it and modifying it accordingly.

4. Deliverables expected for Specific Objective D.

d) A catalog of inventory outcomes for distribution in World Wide Web accessible electronic inventory database along with strategies for maintaining and easily updating the database within 12 months of award.

b) A complete inventory database in a structured electronic form, preferably in extensible markup language (XML) format. This should be accompanied by a final written report that describes the procedures, methodologies and definitions used including full documentation for the electronic inventory database within 15 months of the award. The government has unlimited rights to all data delivered under this contract in accordance with standard government contracting policies

and regulations.

E. Conduct a National Leadership Forum to examine factors promoting and impeding interactivity and expansion of networks; prepare summary of proceedings including strengths and weaknesses of existing models, and proposals for new models.

Tasks and Subtasks: The contractor will be responsible for all activities related to conducting a National Leadership Forum including, but not limited to:

1. Scheduling the Forum sufficiently in advance to ensure maximal participation by key network representatives, NIH staff, and interested members of the scientific community.

2. Arranging meeting logistics including necessary facilities and travel arrangements and providing on-site meeting support.

3. Preparing and distributing meeting agenda and materials sufficiently in advance of the meeting for participants to come prepared for active discussion and problem solving.

4. Preparing and distributing summary and minutes of the Forum within one month of its conclusion.

5. Deliverables expected for Specific Objective E.

a) Schedule the Forum at least 4 months in advance of the date it is to be held, which should be no later than 18 months after contract award.
b) Provide the agenda and materials for the Forum no less than 2 weeks prior to the date of the meeting.
c) Provide a summary and recommendations from the Forum within 1 month of its conclusion.

TECHNICAL EVALUATION CRITERIA AND METHOD OF REVIEW

All proposals received on time will be submitted for technical review by the scientific program office and other NHLBI and NIH staff familiar with the topic of this RFTOP. This review will be arranged and conducted by the Project Officer in conjunction with the Contracting Officer. Following technical review, a written summary of the technical review will be prepared and will be used to advise the Contracting Officer on the proposals that should be considered further. Technical and business questions will be asked of those offerors and discussions will continue until the government requests and

receives final proposal revisions.

Selection of an offeror for award will be based on an evaluation of proposals against technical and cost/price. Technical factors are paramount. Past performance will not be evaluated as a "stand-alone factor" independent of the technical evaluation. Instead, past performance is considered to be a part of the technical evaluation criteria shown below, and in determining an offeror's responsibility in accordance with FAR 9.104-3(b). All evaluation factors other than cost/price, when combined, are significantly more important than cost/price. The trade-off process described in FAR 15.101-1 will be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best value to the Government.

The technical evaluation criteria are used when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Price analysis will be used to verify that the overall price offered is fair and reasonable. Cost/price analysis will be used to evaluate the reasonableness of individual cost elements when cost or pricing data are required. Cost analysis may be used to evaluate information other than cost or pricing data to determine cost reasonableness or cost realism.

TECHNICAL EVALUATION CRITERIA
The criteria below are listed in relative importance with weights assigned for evaluation purposes.

Evaluation Factors	Weight
A. TECHNICAL MERIT	50 Points

Quality and clarity of approach to accomplish the objectives set forth in the Statement of Work. Feasibility of specific plans to address the major goals. Evidence of ability to obtain cooperation from the broad representation of networks needed for this work. Ability to perform the in-depth evaluations of selected networks, as well as to bring the necessary understanding of the issues and current efforts to the larger objectives of the re-engineering of the clinical research enterprise initiative. Evidence of ability to accomplish milestones within the time frame.

B. PERSONNEL 25 Points

Qualifications, experience, and availability of proposed key personnel, and breadth and depth of staff for dealing with all collaborating organizations. Does the proposal provide documentation of competence and experience of professional, administrative, and technical staff pertinent to the objectives being addressed. Is the proposed effort reasonable and appropriate to the technical approach?

C. ORGANIZATIONAL CAPABILITIES, EXPERIENCE AND COMMITMENT AND FACILITIES AND RESOURCES 25 Points

Evidence of organizational capabilities to obtain necessary cooperation from networks and other organizations. Are the institutional experience, proposed administrative structures and responsibilities, and management plan appropriate and supportive of the proposed work? Is the organizational commitment to the project evident and appropriate for all proposed organizations? Are the facilities, resources and equipment adequate?

Automated Information System Security Plan- Solicitation Provision

Information Technology Systems Security, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation.

(a) **Sensitivity and Security Level Designations.**

The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook,* the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will develop or access is categorized as:

[ ] Non Sensitive Information
[ ] Sensitive Information
[ ] Classified Information:
[ ] Confidential **[ ]** Secret **[ ]** Top Secret **[ ]** Special Access

(2) Security Level Designations

http://www.cit.nih.gov/security-policies.htmlThe information that the successful offeror will develop or access is designated as follows:

Level ___ applies to the sensitivity of the data.
Level ___ applies to the operational criticality of the data.

The overall Security Level designation for this requirement is **Level ___**.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).
Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).

[ ] Level 5C: Sensitive - Moderate Risk (Requires Suitability Determination with NACIC).
Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI).

[ ] Level 4C: Classified (Requires Special Access Clearance with an SSBI).
Contractor employees assigned to a Level 4C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 3C: Classified (Requires Top Secret Clearance with an SSBI).
Contractor employees assigned to a Level 3C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 2C: Classified (Requires Confidential or Secret Clearance with an LBI).

Contractor employees assigned to a Level 2C position shall undergo a Limited Background Investigation (LBI).

[ ] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).
Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) **Information Technology (IT) System Security Program**

The offeror's proposal must:

(1) Include a detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed IT systems security program;

(2) Demonstrate that it complies with the AISSP security requirements, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook.

At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a **Security Level _*_** identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.

(3) Include an acknowledgment of its understanding of the security requirements.

(4) Provide similar information for any proposed subcontractor developing or accessing an AIS.

(c) **Required Training for IT Systems Security**

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of

their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: http://irtsectraining.nih.gov/. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors..

(d) **Prospective Offeror Non-Disclosure Agreement**

The Government has determined that prospective offerors will require access to sensitive information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

[ ] Level 6C: Sensitive - High Risk
[ ] Level 5C: Sensitive - Moderate Risk

To be considered for access to this sensitive information, a prospective offeror must:

(1) Submit a written request to the Contracting Officer identified in the solicitation;
(2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
(3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the sensitive information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective

offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(e) **References**

The following documents are electronically accessible:

(1) OMB Circular A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt

(2) DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html

(3) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf

(4) NIH Applications/Systems Security Template: http://cit.nih.gov/security/secplantemp.html

(5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:" http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf

(6) NIH CIT-Policies, Guidelines and Regulations:

Table 1 - Categories of Safeguarded Agency Information: http://irm.cit.nih.gov/security/table1.htm

Table 2 - Security Level Designations for Agency Information: http://irm.cit.nih.gov/security/table2.htm

Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information: http://irm.cit.nih.gov/security/table3.htm

Task Order # NICS-169 TITLE: Inventory and Evaluation of Clinical Research Networks

PART II-CONTRACTOR'S REPLY: CONTRACT #263-01–D-0_____

Contractor:
Address:

Points of Contact:

Phone: Fax:

TOTAL ESTIMATED COST: $ Pricing Method: Cost-Reimbursement

PROPOSED COMPLETION DATE:

FOR THE CONTRACTOR: _____
Signature Date

==========

SOURCE SELECTION:

WE HAVE REVIEWED ALL SUBMITTED PROPOSALS AND HAVE DETERMINED THIS FIRM SUBMITTED THE BEST OVERALL PROPOSAL AND THE PRICE/COST IS REASONABLE:

Billing Reference # _____

Appropriations Data: _____

(ATTACH OBLIGATING DOCUMENT IF A ROC WILL NOT BE USED)

RECOMMENDED: _____
FAX # Signature-Project Officer Date

APPROVED: _____
FAX # Signature-Contracting Officer Date

_____

NIH APPROVAL--

CONTRACTOR SHALL NOT EXCEED THE ESTIMATED TASK ORDER AMOUNT WITHOUT THE WRITTEN APPROVAL OF THE CONTRACTING OFFICER AND ICS COORDINATOR

APPROVED: _____

Anthony M. Revenis, J.D., NIH PICS Coordinator Date