U.S. Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DMID-05-07
International Clinical Sciences Support

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.niaid.nih.gov/contract/default.htm

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** November 15, 2004 **Time:** 3:00 PM, EST	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS #:** 541710 (See Part IV, Section L.)
September 15, 2004		

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	Number of Copies: See Section J Page Limitations: 100 Pages Electronic File Size: 5 mega-bytes

9. **Issued By:**
Barbara A. Shadrick
Senior Contracting Officer
Contract Management Program, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

10. [X] **NIAID reserves the right to make awards without discussion.**

11. **Options:**
[X] No
[ ] Yes (See Part IV, Section L.)

12. **Period of Performance:**
7 years beginning on/about July 20, 2005

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : David T. Lisle **Phone:** (301) 451-2617 **Fax:** (301) 402-0972 **E-Mail:** DL115Q@nih.gov	**Name:** Barbara A. Shadrick **Phone:** (301) 496-7288 **Fax:** (301) 402-0972 **E-Mail:** BS92Y@nih.gov	Program Director, CMP Address (see Block 9.)

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
David T. Lisle, Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	David T. Lisle, Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

TABLE OF CONTENTS

BACKGROUND

International research in infectious diseases is a high priority of NIAID. Infectious diseases spread without regard to national boundaries. NIAID supports investigators studying infectious pathogens that present, or potentially present, significant global public health threats. Environmental and ecological changes, combined with increased global travel, have led to the emergence of traditionally tropical pathogens in new regions.

Infectious diseases disproportionately affect populations residing in developing countries. A 2002 World Health Organization (WHO) report on the impact of infectious diseases (on "Scaling up the Response to Infectious Diseases"; http://www.who.int/infectious-disease-report/2002/framesintro.html) identifies the following leading infectious killers: respiratory diseases (pneumonia, influenza), diarrheal diseases, AIDS, malaria, measles and tuberculosis. More than 40% of deaths in the developing world are directly attributable to infectious and parasitic diseases. HIV/AIDS, TB and malaria claimed 5.7 million lives in 2001. The WHO estimates that 2 billion people worldwide are TB carriers, 8.8 million people develop active TB and 1.7 million die from TB each year. Malaria kills more than 1 million people each year, mostly children under the age of five. Other tropical diseases are a major cause of mortality and morbidity in many parts of the world.

NIH and NIAID maintain a strong commitment to enhance research and research capacity for diseases of global health importance. NIH has expanded its commitment to research on the prevention, control, and treatment of diseases that cause significant health burdens in developing countries. Fulfillment of this mission requires the capacity to carry out research on infectious diseases in endemic areas. NIAID and the Division of Microbiology and Infectious Diseases (DMID) support a spectrum of international research, including clinical studies, to advance the global health research agenda. DMID activities in international research are broad and varied. As of FY2003, the international portfolio included more than 250 projects conducted in more than 60 countries. These activities are funded through grants to investigators at foreign institutions, grants to investigators at U.S. institutions involving international clinical studies and through research groups such as those listed below:

- Bacteriology and Mycology Study Group (BAMSG)
- Collaborative Antiviral Study Group (CASG)
- The Gambia Pneumococcal Vaccine Trial (http://www.niaid.nih.gov/dmid/gambia/study.htm)
- International Centers of Tropical Disease Research (http://www.niaid.nih.gov/ictdr/icidr.htm)
- Malaria Vaccines Clinical Research and Trial Sites in Endemic Areas
- Sexually Transmitted Infections Clinical Trials Group
- Tropical Medicine Research Centers (http://www.niaid.nih.gov/ictdr/tmrc.htm)
- Tuberculosis Research Units (http://www.cwru.edu/affil/tbru/index.htm)

An important aspect of DMID's international health research agenda includes enhancing the capacity to design, conduct, and manage clinical research projects. This solicitation is designed to support DMID's international clinical sites through training and assistance with various aspects of clinical research. The NIAID awarded the "International Clinical Studies Support" contract in 1999 to Family Health International (Contract Number N01-AI-05403 expiring February 28, 2005). This solicitation is a recompetition of that contract.

INTRODUCTION

DMID, NIAID is requesting proposals to establish and maintain an International Clinical Studies Support Center (ICSSC). The primary goal of the ICSSC is to enhance the capacity of international clinical sites to perform clinical research in accordance with international standards, such as the International Conference on Harmonization's (ICH) Good Clinical Practices (GCP), and to facilitate the planning and conduct of clinical evaluations of interventions against infectious disease. Studies that require support include epidemiologic studies and clinical trials that range from small, early phase trials to large multi-center efficacy trials. These studies are conducted throughout the world, primarily in Africa, South and Central America, and Asia.

The contractor will work with NIAID, international investigators, US investigators, and other DMID contractors in completing the activities in the Statement of Work. The work will require that the contractor perform collaboratively with DMID and DMID-funded investigators. The primary focus of this solicitation is assistance and site development activities rather than regulatory compliance or monitoring activities. Other DMID-funded contractors are responsible for regulatory oversight and monitoring of clinical trials and also conduct training and site assessment activities. Thus, there will need to be significant coordination by DMID staff among the activities of these various contractors. The areas in which this contractor will provide assistance to DMID and DMID-funded investigators are:

- Assessment of the readiness of sites to conduct clinical studies,
- Development and design of clinical protocols,
- Training in clinical research design and conduct, including GCP and ethical issues, data management, statistical analysis, and safety monitoring, and
- Logistical/operational aspects of managing the DMID international clinical research portfolio.

Statement of Work
International Clinical Sciences Support
RFP DMID-05-07

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below. All activities of the Statement of Work will require prior approval by the DMID Project Officer, unless otherwise noted.

A. REGULATORY STANDARDS

1. The contractor shall comply with all the United States of America Federally mandated regulatory requirements, with all the Department of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases, and Division of Microbiology and Infectious Diseases policies (to be provided by the Project Officer) and with all the host country regulations applying to the conduct of research involving human subjects; and shall have an approved Federal-wide Assurance on file with the Office for Human Research Protections.

2. The contractor shall follow the International Conference on Harmonization's Guideline for Good Clinical Practice and conduct all human subject research according to the International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the Council for International Organizations of Medical Sciences, or another internationally recognized, comparable Code of Ethics.

B. CLINICAL SITE ASSESSMENT

Assess international sites that conduct clinical research

1. Develop clinical site assessment tools to use when visiting international sites. Collaborate with other DMID contractors under the guidance of the Program Officer to standardize site assessment evaluations.

2. Conduct initial needs assessments and feasibility visits to determine the preparedness of the site(s) to undertake the proposed clinical research. Assessments may include evaluation of the following:

    a. Understanding and ability to implement Good Clinical Practices (GCP) and Good Laboratory Practices (GLP).
    b. Ability to meet relevant U.S., international, and host-country regulatory requirements.
    c. Working knowledge of site staff regarding data collection, entry, and management.
    d. Systems for identification and reporting of adverse events (AEs) and serious adverse events (SAEs).
    e. Infrastructure to support proposed clinical research, such as physical facilities [clinic and waiting areas, laboratories, pharmacy, power backups), connectivity (phone, fax, and internet connections), and institutional capabilities (accounting, data storage systems, Institutional Review Board (IRB) or Ethics Committee (EC)].

3. Analyze and report results of site assessments and make recommendations to DMID regarding clinical site suitability. Recommend any training and/or assistance, identified through the site assessment, that are needed to enhance the research capacity of the site(s).

4. Perform follow-up assessments as needed. These may include:
    a. Study initiation visits,
    b. Visits to assess implementation of previous recommendations,
    c. Site performance and protocol implementation.

C. CLINICAL SITE PREPARATION AND STUDY/TRIAL OPERATIONAL ASSISTANCE

Collaborate with and respond to investigators and/or DMID staff to provide expert advice regarding clinical study/trial design, protocol development, implementation, and logistics.

1. Provide technical assistance, general management and operational support to investigators identified by DMID, and coordinate activities with other DMID operational processes. Activities may include:

    a. Answer study-specific and general questions or forward the questions to appropriate sources for responses.
    b. Assist sites with protocol/study-specific preparedness activities, such as preparation of protocols and related documents. Assist sites with the design, development, writing and review of protocol documents/materials, Investigator Brochures, study manuals of procedures, study–specific procedures, case report forms, and informed consent forms.
    c. Assist sites with study implementation to ensure that clinical studies are conducted in accordance with ICH/GCP guidelines. Assist sites in developing internal quality management systems (quality assurance and quality control) to ensure protocol compliance and that study data are complete and accurate.
    d. Assist sites in the preparation for clinical monitoring. Assist sites with development and implementation of safety monitoring and reporting plans, in accordance with DMID Safety Guidelines.
    e. Provide sites with assistance in designing, developing, validating, and implementing data management and data sharing plans and systems.
    f. Provide expertise to sites related to design, development and conduct of statistical analyses and interpretation.
    g. Provide technical training for hardware/software that are recommended for use.
    h. Develop and use DMID-approved standardized protocol and associated document templates.

2. Provide technical assistance to DMID. Activities include:

    a. Review of protocols, including study design, data management plans, data sharing plans, statistical analysis and evaluations, case report forms, informed consent forms, and logistical feasibility of proposed studies; and
    b. Preparation of materials for submission to a DMID-sponsored Data and Safety Monitoring Board (DSMB) or Safety Monitoring Committee (SMC).

D. TRAINING

Provide training related to the design and implementation of clinical studies/trials for international sites.

1. Perform needs assessments to determine training requirements and the most suitable and efficient mode(s) of providing training (e.g. on-site, via telephone, via teleconferencing or web meeting, via websites).

2. Develop, distribute and update training materials as necessary. Training materials and all updates shall be presented to the DMID Project Officer for approval prior to distribution. Training materials may be required in multiple languages and formats (e.g. hard copy, CD-ROM, web-based).

3. Provide clinical research-related training to investigators and DMID staff to facilitate sound research design and implementation. Training may take different forms, such as workshops, on-line tutorials, or in-depth training at the contractor's facilities. Training may include:

    a. GCP, GLP,
    b. Protocol design and development,
    c. Informed consent, IRB training, and/or safety reporting,
    d. Data management and/or statistical analysis and interpretation,
    e. Scientific writing,
    f. Protocol-specific training, and
    g. Data and system security.

E. GENERAL, LOGISTICAL, AND ADMINISTRATIVE SERVICES TO ASSIST THE DMID/NIAID IN MANAGEMENT OF ITS INTERNATIONAL CLINICAL RESEARCH PROGRAM

Provide programmatic and protocol-specific support that shall include:

1. **Meeting Support**

    a. Includes investigator meetings, protocol meetings, training sessions, DSMB/SMC meetings, and scientific workshops.
    b. Provide comprehensive meeting support to include meeting arrangements, agendas, travel, graphics and video support, logistics and materials preparation and distribution.
    c. Provide meeting summary reports.

2. **Communications**

    a. Establish reliable electronic communication links with DMID and with international sites.
    b. Establish websites for protocol-specific and program communication(s) that shall be implemented with appropriate secured access
    c. Maintain compatibility with standard software.
    d. Initiate conference calls for projects and protocols on an ongoing basis, as well as attend these calls and prepare/distribute minutes.
    e. Arrange for access to web-based meetings.
    f. Provide translation services as required for study-specific and programmatic materials.

3. **Material Distribution**

    a. Provide, develop, review, edit, and distribute DMID-approved program support materials.
    b. Develop and provide study-specific materials as requested by DMID.
    c. Coordinate with DMID staff and clinical investigators on the preparation, printing, and distribution of materials (such as volunteer education materials, recruitment and retention materials including web-based mechanisms, radio and television commercials and printed media.)

4. **Protocol Review Support**

    a. Establish logistical systems to receive, distribute, track, store, and archive protocols submitted from international sites for DMID review.
    b. Develop, provide, and review standard operating procedures for protocol reviews.
    c. Prepare and distribute minutes.

5. **Website**

    a. Develop (using commercial software) and maintain websites necessary to support the international clinical research activities outlined in the Statement of Work.
    b. Website(s) shall provide assistance to DMID-funded investigators and shall also contain restricted-access sites for sharing of information between the Contractor and DMID staff.

6. **Shipping**

    As requested, assist investigators in developing and implementing procedures for shipping specimens; provide specialized operational support for specimen shipping.

F. COLLABORATION WITH OTHER DMID CONTRACTORS

1. Collaborate with other contractors and grantees as requested by DMID. Activities include:

    a. File protocols with the Clinical Trials Management contractor (will be identified after award).
    b. Provide copies of site assessment visit reports to the Clinical Trials Management contractor.
    c. Maintain links with the Clinical Trials Management contractor for Adverse Event/Serious Adverse Event reporting to the DMID Pharmacovigilance Program.
    d. Collaborate with other contractors on development of standardized forms/checklists for site assessment, adverse events reporting, DSMB/SMC submissions.
    e. Collaborate with other contractors and/or grantees in developing and delivering training, particularly related to clinical studies/trials.

G. CONTRACT TRANSITION

1. Develop a written transition plan to ensure the orderly transfer of all or part of this project to a designated Contractor or to the Government. A copy of this plan should be submitted to the Project Officer and Contacting Officer six (6) months prior to the completion date of the contract.

2. Effect a smooth transfer of all databases, data/information, and other files and materials required under the contract to the Government.

[END OF STATEMENT OF WORK]

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

International Clinical Sciences Support
DMID-05-07

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.

In preparing a technical and business proposal in response to this RFP, offerors should:

1. **UNIFORM ASSUMPTION – TOTAL CONTRACT VALUE:** All offerors are directed to assume that $1,000,000 will be available annually to support work under this contract. You are advised to base your business proposal on a Year 1 amount of $1,000,000 and apply inflation accordingly to Years 2 through 7.

2. Include examples of work described in the Statement of Work, such as sample agendas for training classes, site assessment tools, protocol review checklists or checklists.

3. Assume a total of eight site assessment visits per year, two each to South America and Asia and four to Africa, including sub-Saharan Africa.

4. Assume the following studies will require support each year:

   - 30 studies (new and ongoing) will require support
   - 20 new protocols will be developed and reviewed each year, as follows
     - 5 phase II or III clinical trials
     - 3 phase I clinical trials
     - 12 observational, epidemiologic, or natural history studies

5. Assume the following training requirements per year:

   - 1 week long training workshop on clinical research, GCP, protocol development held at an international site, with 35 participants; assume travel reimbursement for all participants from within a general geographical international region (Asia, Africa, or South America).
   - 3 short workshops (2 – 3 days) held at an international site with 20 participants; assume travel reimbursement for all participants from with a general geographical international region.
   - 2 short workshops (1 – 2 days) held in the US in conjunction with a scientific meeting.
   - 2 extended (4 weeks) training opportunities to be held at the contractor's location; assume travel reimbursement.

6. Assume the following logistical and administrative activities will be required per year, in addition to the training activities outlined above:

   - 1 week long scientific meeting in the Washington D.C. area for 80 participants; assume travel reimbursement for 20 international participants.
   - 4 DSMB/SMC meetings held in the Washington D.C area.
   - 2 conference calls per month with DMID staff.
   - 2 conference calls per month with international sites.
   - 2 protocol review meetings per month; 1 via teleconference and 1 with contractor attending in the Washington D.C. area.
   - 2 trips to Washington D.C. area to work with other DMID contractors.

7. Offerors should provide listing of key personnel that will be available for the proposed contract, including consultants. The types of expertise that may be required include, but may not be limited to, epidemiology, biostatistics, clinical trials design, site monitoring, in population and other genomics, data management design, and ethics.

8. Offerors should identify available overseas offices, staff and/or consultants and trainers that speak foreign languages (e.g., Spanish, Portuguese, French, Swahili).

Reporting Requirements
International Clinical Sciences Support
RFP DMID-05-07

REPORTING REQUIREMENTS AND OTHER DELIVERABLES

The contractor shall submit to the Contracting Officer and the Project Officer technical progress reports covering the work accomplished during each reporting period.

A. Technical Reports

1. Semiannual Technical Progress Reports – By the 15th calendar day of the month following the end of each six (6) month period, the Contractor shall submit three (3) copies of a Semiannual Technical Progress Report, comprising two (2) copies to the Project Officer and one (1) original to the Contracting Officer. Semiannual Reports are not due for periods in which an Annual or Final Report is due. Such reports shall include the following specific information:

    a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission;
    b. SECTION I - An introduction covering the purpose and scope of the contract effort;
    c. SECTION II - A description of overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the report period. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;
    d. SECTION III - Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and corrective steps should be provided;
    e. An anticipated work plan for the following 6 months;
    f. Copies of materials such as conference call minutes, summaries of protocol reviews, workshop agendas, etc. shall be submitted along with the report.

2. Annual Technical Progress Reports – By the 30th of the month following each anniversary date of the contract, the Contractor shall submit three (3) copies of an Annual Technical Progress Report, as above, comprising two (2) copies to the Project Officer and one (1) original to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. A summary of work proposed for the next reporting period should also be included in the report. A one page summary of each ongoing and completed protocol shall be submitted at this time. An Annual Report will not be required for the period when the Final Report is due. Preprints and reprints of papers and abstracts not submitted in the semiannual report shall be submitted.

3. Final Report and Summary of Salient Results - On/before the completion date of the contract, the Contractor shall submit three (3) copies of a comprehensive Final Report, comprised of two (2) copies to the Project Officer and one (1) original to the Contracting Officer. This Final Report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Preprints and reprints not included previously shall be submitted. The Contractor shall submit with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

4. Transition Plan – Six (6) months prior to the contract completion date, the Contractor shall submit a written transition plan, subject to the Project Officer approval, to ensure the orderly transfer of all or part of this contract to a designated Contractor and/or the Government. The Contractor shall provide three (3) copies of the Transition Plan, comprised of two (2) copies to the Project Officer and one (1) original to the Contracting Officer.

B. Other Deliverables

Other deliverables are identified throughout the Statement of Work that are to be submitted only to the Project Officer during the entire contract period of performance. The due dates for these deliverables will be negotiated at the time the request is made by the Project Officer. In general, reports from site assessment visits will be due 15 working days after completion of the visit.

C. If the Contractor becomes unable to deliver the reports or other deliverables specified here within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons. Prior to the original due date, the Contractor must submit, along with this notification, the revised date of submission, subject to approval of the Project Officer and Contracting Officer.

D. Copies of the technical reports shall be submitted as follows:

Item	Deliverable	No. of Copies	Delivery Date
1.	Semiannual Report	1 Original – C.O. 2 Copies – P.O.	Due on/before the 15th of the month following each 6-month reporting period. The first report shall be due on (date TBD).
2.	Annual Report	1 Original – C.O. 2 Copies – P.O.	Due on/before the 30th of the month following each anniversary date of the contract. The first report shall be due on (date TBD).
3,	Final Report	1 Original – C.O. 2 Copies – P.O.	Due on/before the completion date of the contract.
4.	Summary of Salient Results	1 Original – C.O. 2 Copies – P.O.	Due with the Final Report.
5.	Transition Plan	1 Original – C.O. 2 Copies – P.O.	Due 6 months prior to the completion date of the contract.

E. Addressees

Project Officer
DMID, NIAID, NIH
6610 Rockledge Drive
Room 6005, MSC 7630
Bethesda, MD 20892-7630

Contracting Officer
CMP, DEA, NIAID, NIH
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES

The complete listing of these clauses may be accessed at: http://rcb.cancer.gov/rcb-internet/clauses/clauses.html

The following General Clause Listings will be applicable to most contracts resulting from this RFP. However, the organizational structure of the successful offeror(s) will determine the specific General Clause Listing to be contained in the contract(s) awarded from this RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

ITEM 9: **Alternate II** (OCTOBER 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (OCTOBER 2001) is added.

See **I.2 Authorized Substitutions of Clauses** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Authorized Substitutions of Clauses.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

ITEM 34: FAR Clause **52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns** (JUNE 2003), is applicable to this solicitation as follows:

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10 percent to the price of all offers, except--...".

Offerors will be evaluated by adding a factor of 10% to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

ITEM 35: FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (OCTOBER 1999), is applicable to this solicitation.

ITEM 46: The following Alternate is applicable to this solicitation:

Alternate I (JUNE 1987), **FAR Clause 52.227-14, Rights in Data--General** (JUNE 1987).

ITEM 54: FAR Clause **52.237-3, Continuity of Services** (JANUARY 1991), is applicable to this solicitation.

See **I.3 Additional Contract Clauses of** SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional Contract Clauses.

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

See **I.4. Additional FAR Contract Clauses Included in Full Text** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional FAR Contract Clauses Included in Full Text.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS: (http://www.niaid.nih.gov/contract/eproposal.htm#pack)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (http://www.niaid.nih.gov/contract/eproposal.htm#electronic)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: October 6, 2004] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMP's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Privacy Act System of Records**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Please refer to http://www.niaid.nih.gov/contract/eproposal.htm for delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided at the above-referenced weblink. You must certify that both the original paper and electronic versions of the proposal are identical.

The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE. -- SUBMISSION OF ONLY ELECTRONIC PROPOSALS WITHOUT PAPER COPIES IS NOT ACCEPTABLE.

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

NUMBER OF COPIES:

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	Limited to not-to-exceed 100 pages.	Limited to not-to-exceed 5 mega-bytes
Technical Proposal Appendices All materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	This information is included in the total Technical Proposal page limit.	N/A
Business Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Ten (10) bound copies.	Limited to not-to-exceed 100 pages	Limited to not-to-exceed 5 mega-bytes
Representations and Certifications	One (1) Original required to be submitted with the Original Business Proposal. (Extra copies are optional.)	N/A	N/A
All offerors are required to submit three (3) CDs that each contain electronic versions of all proposal information (both technical and business – clearly named). If information appended to the paper version is not available electronically, the CD shall contain a file listing all documents that are submitted in paper format only. **The offeror shall include certification that the documents provided electronically match the paper version of those same documents.**		Technical Proposal: 2 Compact Discs (CDs) Business Proposal: 1 Compact Disc (CD)	

THE TECHNICAL PROPOSAL LIMIT INCLUDES: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. **PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.**

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is a limit of ten (10) megabytes to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Documents must be converted to a .pdf searchable format.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 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. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT RESPONSE SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1.	Log-in Site:	Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2.	Log-in Name:	Will be provided by the Contract Specialist via e-mail.
3.	Log-in Password:	Will be provided by the Contract Specialist via e-mail.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-05-07
RFP Title: "International Clinical Sciences Support"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by October 6, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMP, NIAID, NIH
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: David T. Lisle
RFP-NIH-NIAID- DMID-05-07
FAX# (301)
Email : DL115Q@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

I. GENERAL INFORMATION

ITEM 2: **Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISTION,** is applicable to this solicitation.

ITEM 9: **NAICS CODE AND SIZE STANDARD**

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

(1) The NAICS Code is 541710.
(2) The small business size standard is 500 employees.

ITEM 11: **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

Offerors will be evaluated by adding a factor of 10% to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

ITEM 12: **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about July 20, 2005.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type completion contract with a period of performance of 7 years , and that incremental funding will be used [see Section L, PART IV - Business Proposal Instructions].

ITEM 14: **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 4 full time equivalents (FTEs). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

ITEM 17: **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

ITEM 21: **LATE PROPOSALS AND REVISIONS,** HHSAR 352.215-70, is applicable to this solicitation.

II. GENERAL INSTRUCTIONS

ITEM 24: **Potential Award Without Discussions,** is applicable to this solicitation.

ITEM 34: **Small Business Subcontracting Plan,** is applicable to this solicitation.

ITEM 36: **Extent of Small Disadvantaged Business Participation,** is applicable to this solicitation.

ITEM 38: Salary Rate Limitation in Fiscal Year 2004, is applicable to this solicitation.

ITEM 41: Past Performance Information is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the Business proposal.

A list of the last five contracts completed during the past three years and currently in process that are similar in nature to the solicitation workscope.

ITEM 50: Prohibition on Contractor Involvement with Terrorist Activities, is applicable to this solicitation.

ITEM 51: Solicitation Provisions Incorporated by Reference: The following provisions are applicable to this solicitation.

Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

III. TECHNICAL PROPOSAL INSTRUCTIONS

ITEM 53: Project Objectives, NIH-1688-1, is applicable to this solicitation.

ITEM 56: 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:

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

(2) Security Level Designations

The information that the successful offeror will develop or access is designated as follows:
Level 1C Non Sensitive applies to the sensitivity of the data.
Level 1C Non Sensitive applies to the operational criticality of the data.

The overall Security Level designation for this requirement is **Level 1C Non Sensitive**.

(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).

[x] 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 1C Non Sensitve** 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) **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

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 58: **Proposal Cover Sheet,** is applicable to this solicitation.

ITEM 59: **Information Other than Cost or Pricing Data,** is applicable to this solicitation.

[x] This information may be submitted in the offeror's own format.

ITEM 61: **Cost and Pricing Data** is applicable to this solicitation.

Subparagraph 3. Formats for Submission of Line Item Summaries:

[x] The format specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf is applicable to this solicitation.

ITEM 62: **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)],** is applicable to this solicitation.

ITEM 67: **Incremental Funding,** is applicable to this solicitation.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may 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 overall value to the Government.

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. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Proposals submitted in response to this RFP will be evaluated based on the following factors. Proposals will be judged solely on the written material provided by the offeror and the information gathered by the Contracting Officer concerning past performance. It is anticipated that one award will be made as a result of this acquisition, dependent on the availability of funds.

OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO SECTION L.2.c. OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATON RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

CRITERIA	**WEIGHT**
A. Technical Approach	**40 points**

The adequacy and feasibility of the proposed technical approaches, including alternative strategies and identification of potential obstacles and solutions for such obstacles in the performance of all the requirements of the statement of work. This will include the following:

1. Providing assistance to clinical sites in the preparation and implementation of clinical studies, and to DMID for study protocol review and other study-related activities. This includes the participation in review of site operations, protocol and adjunctive document development and review, establishment of internal quality control/quality assurance programs, data management, safety monitoring, statistical analysis, and other study-related components.
2. Conducting clinical site assessments and related activities at international sites.
3. Providing training related to design and implementation of clinical studies in international settings.
4. Providing general and protocol-specific clinical research management of a global portfolio of DMID international studies, including research program management support, meeting management and communications activities.
5. Adequacy of understanding with regulatory standards and their applications in international settings.
6. Contract transition plan.

B. <u>Qualifications and Availability of Proposed Scientific and Management Staff</u> 30 points

Adequacy and feasibility of the proposed staffing for the conduct of the project, including the appropriateness of the time commitments of the proposed positions, the clarity and appropriateness of assigned roles, responsibilities, lines of authority (provide an organizational chart that includes all personnel), plans for back-up staffing as the need arises, and the logistical adequacy of the proposed staffing plan. Offerors should provide appropriate and multi-disciplinary staff with relevant experience in a broad range of clinical research management associated with the planning, implementing and conduct of epidemiologic studies and Phase I-IV clinical trials in international settings.

1. Principal Investigator, Leadership and Management Structure 15 points

   Adequacy of the documented training, experience, leadership, and availability of the Principal Investigator (and co-Principal Investigator if relevant), including international research program management experience, epidemiologic and clinical trials expertise, and experience with providing training in resource constrained settings. Adequacy and feasibility of the administrative framework including clear lines of authority and responsibility for the overall DMID international clinical research program support as well as protocol-specific support.

2. Professional and Technical Staff 15 points

   Adequacy of the documented training, experience, capability and availability of the proposed professional, research, technical, management, and support staff to perform the tasks outlined in the Statement of Work. Adaquacy of the documented expertise in similar projects, with a special emphasis on their ability to anticipate the variety of special conditions likely to be encountered, especially among resource constrained sites, . Adequacy of the documented understanding of the technical staff's of clinical research requirements and Good Clinical Practices.

C. <u>Organizational Experience, Facilities and Resources</u> 30 points

Adequacy of the documented overall experience of the organization in conducting similar types of projects and providing the facilities and services required to complete the work outlined in the Statement of Work.

1. Experience in managing and supporting a variety of international clinical studies and clinical trials, particularly in resource-constrained settings
2. Organizational experience in providing training related to GCP, clinical research, and related activities in an international setting.
3. Capacity and capability to work with DMID staff, DMID-funded grantees and contractors, as well as possess the ability to establish the necessary linkages (administrative, logistic, operational, etc.) as required for sound clinical research management and support.
4. Documented availability and adequacy of facilities, equipment, and resources necessary to effectively carry out all phases of the proposed project.

TOTAL:
100 Points

3. **PAST PERFORMANCE FACTOR**

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

4. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent of commitment to use SDB concerns
(b) Realism of the proposal
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.