U.S. Department of Health and Human Services
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DAIDS-05-16
DAIDS Virology Quality Assurance

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:** January 5, 2005 **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.)
October 29, 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:**	10. [X] **NIAID reserves the right to make awards without discussion.**	
Barbara A. Shadrick Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[ ] No** **[X] Yes** (See SOW and Part IV,Section L.)	12. **Period of Performance:** 7 years beginning on/about August 15, 2005

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Lola Kellum **Phone:** 301-451-7367 **Fax:** 301-402-0972 **E-Mail:** kelluml@niaid.nih.gov	**Name:** Lisa Coleman **Phone:** 301-451-3682 **Fax:** 301-480-5253 **E-Mail:** lcoleman@niaid.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**
Lola Kellum Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Lola Kellum 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.

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BACKGROUND

The mission of the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) is to help ensure an end to the HIV/AIDS epidemic by increasing basic knowledge of the pathogenesis and transmission of the human immunodeficiency virus, or HIV, supporting the development of therapies for HIV infection and its complications, and supporting the development of vaccines and other prevention strategies. This mission is carried out by three Programs: the Basic Sciences Program (BSP), the Therapeutics Research Program (TRP) and the Vaccine and Prevention Research Program (VPRP).

The purpose of this Contract is to continue an ongoing quality assessment program for virologic assays performed on samples from subjects enrolled in DAIDS-sponsored multi-site clinical studies. The Virology Quality Assurance (VQA) Program is critical to the scientific integrity of on-going and future studies concerning HIV diagnosis, disease progression, assessment of treatments, vaccine efficacy and other preventive measures. The VQA has been in operation since 1988 and has developed and standardized quality control procedures for approximately 25 virologic assays used in DAIDS-sponsored clinical trials. The history of this Program is as follows:

1988 – 1993 Initial award to Baylor College of Medicine, Houston, TX
1993 – 1998 Award to Rush Presbyterian St. Luke's Medical Center, Chicago, IL
1998 – 2005 Award to Rush Presbyterian St. Luke's Medical Center, Chicago, IL

To ensure the validity and inter- and intra-laboratory comparability of virologic laboratory data obtained from DAIDS-supported clinical trials and HIV natural history studies, the Contractor will continue a program for "Real-Time Assay Validation," where known quality control materials (QCMs) are tested by VQA-supported laboratories (hereafter referred to as Sites) in parallel with patient samples to ensure the validity of each assay "run." The Contractor will also conduct a "Proficiency Testing" (PT) program, where unknown QCMs are tested by the Sites to periodically monitor Site assay performance. The Contractor will provide participating Sites with standardized reagents and controls for conducting research aimed at development and evaluation of virologic and statistical methodologies.

The VQA Program will serve current and future DAIDS-sponsored clinical trial networks and collaborating study groups (User Groups). Currently supported User Groups include: the Adult AIDS Clinical Trials Group (AACTG), the Pediatric AIDS Clinical Trials Group (PACTG), the HIV Vaccine Trials Network (HVTN), the Women and Infants Transmission Study (WITS), the Women's Interagency HIV Study (WIHS), the Multicenter AIDS Cohort Study (MACS), the Community Program for Clinical Research on AIDS (CPCRA), the HIV Prevention Trials Network (HPTN), the Comprehensive International Program of Research on AIDS (CIPRA), the Acute Infection and Early Disease Research Program (AIEDRP), as well as other domestic and international individual grantees. Collaborations are anticipated with CDC Global AIDS Program (GAP)-affiliated laboratories supporting the President's Emergency Plan for AIDS Relief (PEPFAR) activities.

Currently, the VQA program serves approximately 55 domestic and 25 international Sites. (See Appendix D for the locations of current Sites). The base Contract is expected to cover these 80 Sites. Although the structure of the clinical trial networks is subject to change during the Contract period, the changes are not expected to result in changes to the number of participating Sites in the base Contract. However, the Government anticipates a need to expand the number of Sites during the course of the Contract, and such an increase in the Contractor's activities may be activated, at the discretion of the Government, as one or more Options in each of the Contract years. See Appendix B for additional information regarding the options.

APPENDIX A ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

APPENDIX B ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM BUDGET ASSUMPTIONS

APPENDIX C COMPUTER SYSTEMS

Most, but not all, Sites are currently linked through an electronic network which is used to transmit virology data from the Sites to a remote Central Database. Sites are also using a customized laboratory data management system (LDMS) that tracks specimens, provides assay templates, calculates derived quantities, produces reports, and generates data files for export from the Site.

The successful offeror will be required to provide some VQA-related information through the DAIDS-ES. While some of this may be accomplished through a link from DAIDS-ES to the VQA web site, some data may need to be shared by the VQA, with DAIDS ES, in which case data sharing agreements, standards, etc. will be required.

APPENDIX D SITE LOCATIONS

A list of the location of all active international participating sites.

APPENDIX E GOVERNMENT-FURNISHED MATERIALS/PROPERTY

A list of all government furnished equipment that will be transferred to the successful offeror.

STATEMENT OF WORK
DAIDS Virology Quality Assurance

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities not otherwise provided by the Government as needed to perform the Statement of Work set forth below.

Specifically the Contractor shall perform the following tasks:

A. Implement standards of performance for existing and newly developed virologic assays and assess the ability of Sites to successfully perform the assays.
B. Conduct studies on the adaptation, standardization and application of new and existing virologic and biostatistic methodologies.
C. Acquire, characterize, store, document and disburse quality control materials and reagents to include biohazardous materials and infectious agents.
D. Disseminate Virology Quality Assessment technical and scientific data.
E. Maintain computerized software systems that support the VQA Program.
F. Expand services to include additional Sites when necessary through exercise of Options.
G. Implement a transition plan at the end of the contract.

A. IMPLEMENTATION OF VIROLOGY SITE PERFORMANCE STANDARDS AND SITE ASSESSMENT

1. PROFICIENCY TESTING (PT)

Sites are tested to ensure proficiency in performing assays. Proficiency is determined through evaluation of results obtained with coded (unknown to Sites) Quality Control Materials, hereafter referred to as QCMs. Panels of QCMs are tested by the Sites on a regular basis. For each assay specified by the Project Officer, the Contractor shall:

a. Provide participating Sites with coded QCMs, at intervals specified by the Project Officer. Paragraph C., below, provides further information on QCMs. Examples of PT QCMs include:

1) serum/plasma samples (from HIV-positive donors and/or spiked normal serum) containing known numbers of HIV RNA copies/ml for RNA quantification;

2) whole blood from well-characterized donors, HIV-positive and HIV-negative, for qualitative HIV cultures, DNA PCR assays and genotypic drug resistance assays;

3) frozen cell pellets from HIV-negative donors spiked with known amounts of HIV-positive cells for DNA PCR assays;

4) serum/plasma samples (from HCV-positive donors and/or spiked normal serum) containing known numbers of HCV RNA copies/ml for RNA quantification and/or genotyping; and

5) semen and vaginal/cervical secretions from HIV positive donors and/or spiked normal materials for viral quantification and genotyping in genital secretions.

b. Provide the Sites with instructions (written and/or via electronic mail) regarding:

1) use of QCMs in assays;

2) storage of QCMs at the Site;

3) method and format of PT performance and reporting; and

4) deadlines for, and method of, reporting of PT results.

c. Retrieve PT results by accessing the PT data entered into the Laboratory Data Management System (LDMS) and forwarded to the Central Database after completion of each round of testing. Paragraph E and Appendix C, below, provide additional information on computer systems, the LDMS, databases and electronic communication. See, also, APPENDIX C.

d. Analyze assay performance results from the Sites and determine successful performance based on criteria formulated by the Contractor, relevant User Groups and the Project Officer. Evaluation factors may include statistical parameters such as goodness of fit, deviation around a mean, and coefficient of variation, as applicable to particular assays.

e. Provide, via electronic mail, each Site with its own Site-specific preliminary report of the PT results (provisional performance status), five working days following data receipt from all participating Sites. The Contractor shall review the data for accuracy and completeness and discuss the PT results with the Project Officer in conference calls. Upon determination of Site performance status, a hard copy report shall be submitted to the Sites, the Project Officer and others, as requested by the Project Officer. The Contractor shall include results of performance evaluations in the Quarterly Progress Report.

f. Provide a software system to track and support the activities required for PT. See Paragraph E, below, for information on computer systems.

2. **REAL-TIME ASSAY VALIDATION**

To ensure assay validity, the VQA provides sites with QCMs for use as external controls in each assay run. QCM assay results falling outside predetermined ranges indicate an invalid assay. For each virologic assay that requires on-going, real-time validation the Contractor shall:

a. Provide the Sites with known QCMs to be used in real-time run validation. The amounts of QCMs needed may vary from Site to Site depending upon number and frequency of tests performed. Sites are responsible for maintaining an internal "reagent inventory" and for communicating their QCM needs to the Contractor. Frequency of shipments is determined by the stability (expiration date) of QCMs. Examples of QCMs include:

1) viral lysates with known concentrations of HIV p24 antigen, for HIV p24 Ag capture assays used to determine positivity of HIV cultures;

2) cell pellets with known DNA copy number for use in DNA PCR assays; and

3) cell-free virus preparations of known concentration for RNA PCR assays.

Paragraph C., below, provides further information on QCMs.

b. Provide the Sites with instructions (written, telephonic or via electronic mail) regarding:

1) use of QCMs in assays;

2) storage of QCMs; and

3) method of real-time validation of assay results.

c. Update and maintain a computerized database to track and support the activities required for real-time assay validation. Paragraph E., below, provides further information on computerization.

3. **SITE ASSISTANCE AND TRAINING**

a. The Contractor shall train Site personnel. Specifically, the Contractor shall:

1) Provide Sites with procedures/instructions (electronic or hard copy) for performing virologic assays, prepare training materials (e.g. assay protocols, instructional videos, diagrams and pictures), and make training materials available on the VQA web site. Paragraph E., below, provides information on the VQA web site.

2) Organize workshops for state-of-the-art virologic technologies held at the Contractor's site or other suitable locations. The Contractor shall provide the teaching staff and materials required for "hands-on" training/demonstrations.

3) The Contractor shall not be responsible for travel costs of participants.

b. Upon identification of Sites whose results deviate from accepted values agreed upon by the Contractor, User Groups and the Project Officer, the Contractor shall provide assistance to the Sites in order to help improve assay performance. Specifically, the Contractor shall:

1) Identify and quantify sources of variability and/or other reasons for such performance by direct inquiry or by survey.

2) Recommend measures to assist Sites with results that deviate from accepted values. The Contractor shall monitor the implementation of the recommended actions, and subsequent assay performance. The Contractor shall:

a) provide Sites with additional written, telephonic or electronic instruction;

b) make arrangements for visits to the Contractor by Site personnel for the purpose of training (Sites will be responsible for their own travel expenses);

c) travel to Sites to investigate results that deviate from accepted values and implement corrective action; and

d) describe assistance provided to the Sites in the Quarterly Progress Report.

3) Provide Sites with additional QCM panels for re-testing after implementation of corrective measures. Analyze data from the additional panels and report results to Sites and to the Project Officer.

B. ADAPTATION, STANDARDIZATION AND APPLICATION OF VIROLOGIC AND BIOSTATISTICAL ANALYTICAL METHODOLOGIES

To ensure the continued development of virologic assays and their application to vaccine, prevention and therapeutic studies, the Contractor shall conduct studies to optimize new or existing virologic methodologies, and investigate and integrate biostatistical methodologies for the evaluation and interpretation of laboratory data.

1. VIROLOGIC ASSAY METHODOLOGIES

a. The Contractor shall conduct multi-site studies to:

1) Evaluate up to four existing or newly developed virologic assays per year. For each evaluation the Contractor shall provide up to ten selected Sites with assay-appropriate coded QCMs (eg. viral sub-type RNA panels, spiked genital secretion samples, ultra-ultra low HIV RNA panels, panels of HIV with known levels of minor variants, panels of blood spots for DNA PCR, and well-characterized patient specimens). Examples of assays that may be evaluated include, new assays for quantitative detection of all subtypes of HIV and HCV, assays for quantitative detection of minor variants in clinical samples, assays to detect spliced or unspliced viral RNA and integrated vs. unintegrated viral DNA in various cell and tissue types, assays for virus quantification and resistance genotyping in genital secretion samples; assays for RNA quantification on samples with <50 copies of RNA/ml..

2) Compare commercial or specific laboratory-based assays, assay kits or reagents. Up to four such comparisons will be performed per year. For each comparison, the Contractor shall provide up to ten selected Sites with appropriate known standards and coded QCMs (e.g. panels of subtype B and non-B isolates for genotypic analysis, HIV RNA panels, and whole blood panels for HIV culture). Examples of comparison studies include: comparison of several commercial and in-house genotypic resistance assays to one another; comparison of different versions of a commercial RNA quantification kit; comparisons of different fetal bovine serum lots for use in HIV cultures; comparisons of kit sensitivity and specificity for non-subtype B viruses; comparisons of simplified viral load test kits vs. standard RNA quantification kits.

3) Evaluate and compare specimen handling, processing, and storage procedures. Up to four such studies will be performed per year. For each study, the Contractor shall provide up to 10 selected Sites with appropriate known standards and coded QCMs. Examples include: studies of the effect of anticoagulant on HIV RNA assays, studies of the effect of shipping temperature on HIV RNA assays, stability of HIV RNA in plasma stored at different temperatures.

b. Provide and maintain a software system that supports virologic assay research and development activities described in Paragraph B.1.a., above. Paragraph E., below, provides further information on computerization.

c. Assemble and statistically analyze data from the above-mentioned studies (Paragraph B.1.a., above) and forward results to the Project Officer and relevant User Group(s). All such results shall be included in the Quarterly Progress Report. Studies may require electronic data capture for analysis (e.g. inter- and intra-Site variability, and sensitivity/specificity of the assays). Paragraph E., below, provides further information on computerization.

2. **ANALYTICAL AND BIOSTATISTICAL METHODOLOGIES**

Collaborate with appropriate User Groups and statisticians to evaluate and apply existing or novel statistical models for assessment, interpretation, and validation of virologic assay test results. The Contractor shall:

a. Develop, with the Project Officer and User Groups, quality control parameters for up to four new assays per year as they are implemented in clinical studies. For example, develop statistical methods to ensure quality control of sequence data from genotypic drug resistance proficiency panels. Paragraphs A.1. and A.2., above, discuss PT and real-time assay validation.

b. Develop approaches to statistical analysis and interpretation of data from up to four virologic assays per year. An example would be development of methods to evaluate genotypic drug resistance assay results.

c. Develop approaches for using assay calibration data for determination of detection limits or cut-off values for up to four assays per year. An example would be development of algorithms for determining the lower limit of detection for quantitative HIV or HCV RNA assays.

d. Develop criteria for evaluating real-time assay validation at the Sites for up to 2 assays per year. These will include statistical methodologies that compare intra- and inter-Site variation. An example would be Levy-Jennings or similar plots that measure intra-Site variability over time (monthly). These may be combined with plots that assess one Site's performance in relation to other Sites.

e. Develop statistical models for up to four virologic assays per year to measure the effect of possible variations of assay parameters on assay precision and outcome. Examples of possible assays are indicated in Paragraph B.1., above.

C. **PROVISION OF QUALITY CONTROL MATERIALS/REAGENTS**

Procure materials and reagents necessary for production of QCMs, prepare and characterize the QCMs and provide the Sites with QCMs and other reagents needed to support work outlined in Paragraphs A. and B., above. Materials and reagents will include biohazardous materials (i.e. bloodborne pathogens including HIV, HCV and others).

1. **DONOR PROGRAM**

The Contractor shall develop and maintain a donor program for obtaining materials from well-characterized infected (e.g. known CD4 and CD8 cell counts, HIV and/or HCV RNA levels, CBC, hepatitis) and uninfected human subjects. The donor pool must allow for the acquisition of materials from volunteer donors infected with each known subtype of HIV and relevant subtypes of other viruses. Donor materials shall include whole blood, serum, plasma, PBMC, and genital secretions. In support of this program the Contractor must:

a. comply with all applicable domestic and international regulations on the use of human subjects in research; and

b. comply with HIPAA and Privacy Act requirements.

2. **ADDITIONAL QCMs/REAGENTS**

The Contractor shall produce or obtain additional reagents as needed for QMCs (e.g. infected cell lines, viral lysates, viral stocks, enzymes). These shall be obtained from research institutions or commercial sources, domestic or international.

3. **CHARCTERIZATION OF QCMs**

Prior to use in laboratory performance or in assay/kit evaluation studies, the Contractor shall determine QCM and reagent characteristics, and their optimal use and storage conditions. Examples include:

a. concentration of infected cells in frozen cell pellets;

b. HIV-1 RNA levels in spiked plasma or other samples;

c. p24 antigen levels of viral lysates; and

d. effect of reagent handling conditions (e.g. length of storage, storage temperature and shipping temperature and time) on stability and activity.

4. **STORAGE OF QCMs**

The Contractor shall store aliquots of characterized QCMs and reagents under conditions that ensure continued activity and viability of materials.

5. **QCM/REAGENT SHIPPING**

Upon Project Officer approval, the Contractor shall ship QCMs/reagents to specified domestic and international destinations under appropriate shipping conditions (e.g. temperature monitoring) and in accordance with IATA/ICAO dangerous goods shipping regulations and other relevant shipping regulations. In addition:

a. execute agreements with receiving institutions regarding relevant standards for safe handling and authorized use of QCMs/reagents;

b. arrange overnight (or fastest possible) delivery of shipments to the Sites. The Contractor shall obtain the appropriate interstate, intrastate and foreign shipping licenses and permits for transporting biohazard materials; and

c. coordinate the shipments of QCMs/reagents to the Sites, including prior notice of upcoming shipments.

6. **SAFETY AND HEALTH**

The Contractor shall provide Contractor personnel with protective garments, equipment, training and sufficient monitoring to assure safe handling of potentially hazardous and infectious materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein. The Contractor shall follow all safety and health regulations in accordance with HHSAR 352.223-70.

7. **FACILITIES**

The Contractor shall provide facilities and equipment to accommodate acquisition, characterization, storage and distribution of potentially hazardous materials. As such, the Contractor shall:

a. Provide sufficient space to accommodate:

1) QCMs/reagent storage units (e.g. ultra-low freezers, liquid nitrogen tanks, freezers, refrigerators, back-up freezers);

2) laboratory work area that includes Biosafety Level 2 containment, Biosafety Level 2/3 containment for culture of HIV, and sterile conditions for QCMs/reagent testing and processing;

3) office and packaging area; and

4) private room for donor specimen collection.

b. Provide emergency backup measures in order to ensure the continuous activity and viability of QCMs and reagents. At a minimum, such measures shall include equipment alarm systems, equipment maintenance services, backup power supply.

c. Provide security measures that ensure the facility and equipment against fire and personal intrusion.

8. **QCMs/REAGENT DOCUMENTATION**

The Contractor shall:

a. Summarize in the Quarterly Technical Reports activities related to QCMs/reagents acquisition, characterization, storage and distribution.

b. Maintain a computerized software system for the documentation of all QCMs and reagents. Paragraph E., below, provides further information on computerization.

D. **DISSEMINATION OF VIROLOGY QUALITY ASSESSMENT TECHNICAL AND SCIENTIFIC DATA**

The Contractor shall, on approval of the Project Officer, disseminate technical and scientific data that result from activities conducted under this Contract through publication and presentation of data and through conference calls and meetings with relevant parties. Scientific presentations will include data originating from field testing of virologic assays, assessment of assay parameters, evaluations of commercial kits, comparative studies of methodologies, and other studies.

1. **PUBLICATION AND PRESENTATION OF DATA**

The Contractor shall:

a. Prepare, within 3 months of study completion, materials to support preparation of scientific manuscripts for publication in peer reviewed journals, and submit these materials to the Project Officer.

b. Present data at DAIDS-sponsored meetings, and at domestic and international scientific meetings as approved by the Project Officer.

c. Provide DAIDS-sponsored User Groups with consensus protocols for virologic assays, distributing them to Sites, and compiling them into a hard copy and electronic manual.

d. Post quality assessment technical and scientific data on the VQA web site (e.g. results of assay comparison studies, new assay protocols, changes to assay protocols, changes to reagent storage and handling characteristics). Paragraph E., below, provides information on the VQA web site.

2. **CONFERENCE CALLS AND MEETINGS**

The Contractor shall:

a. Participate in weekly conference calls to include the Project Officer, the Principal Investigator, the Project Manager, statisticians and other VQA personnel specified by the Contractor or the Project Officer.

b. Participate in conference calls with Sites working on assay development. When necessary, schedule conference calls; the cost of which will be charged to the contract.

c. Meet with the Project Officer at least twice per year to review progress, anticipated or existing problems, and to discuss the work to be performed. The schedule and location of such meetings/site visits shall be determined by the Project Officer. The Contractor shall make facility and meeting arrangements for annual visits to the Contractor's site by the Project Officer.. Meeting arrangements shall be approved in advance by the Project Officer.

E. **COMPUTERIZED SOFTWARE SYSTEMS**

The Contractor shall provide state of the art software systems for data management in support of the VQA program. The Contractor shall be responsible for the purchase of all general purpose ADP equipment and related maintenance agreements.

1. **PT AND REAL-TIME ASSAY VALIDATION DATA TRACKING SYSTEM**

The Contractor shall provide a software system to track and support the activities required for Proficiency Testing (PT) and real-time assay validation (Paragraphs A.1. and A.2., above). Existing data will be transferred from the current contractor in the form of spreadsheets. Data to be compiled includes:

a. participating Site contact information;

b. assay systems, e.g. DNA PCR, genotypic resistance testing;

c. type, amounts, characteristics and lot numbers of QCMs provided for PT;

d. relevant dates, such as QCMs shipping date to Sites, QCMs testing date;

e. Quality Control data; and

f. PT performance and certification status of Sites.

2. **ASSAY RESEARCH AND DEVELOPMENT DATA SYSTEMS**

The Contractor shall provide software systems that support virologic assay research and development activities (Paragraph B.1., above) including software systems that support biostatistical analyses (Paragraph B.2., above). Electronic data capture may be required. Any software used to capture or analyze data shall be designed in a format that will easily permit further development and inclusion in the LDMS, should the assays be implemented in clinical trials and performed on patient specimens. Existing data will be transferred from the current contractor in the form of spreadsheets. Data to be compiled includes:

a. relevant information about materials used;

b. list of testing Sites; and

c. assay results and data analysis.

3. **QCM DATA TRACKING SYSTEM**

The Contractor shall provide a computerized software system that tracks QCM data. Existing data will be transferred from the current contractor in the form of spreadsheets. Data to be compiled includes:

a. relevant information for each acquired QCM/reagent, including source/donor, description, lot number, date manufactured or obtained, storage conditions and location;

b. characterization data for each QCM/reagent,, such as RNA copy numbers, p24 antigen concentration, DNA copy number, neutralization titers, optimal conditions for use in assays;

c. storage information for each QCM/reagent such as length of time in storage, temperature of storage and number of times frozen and thawed; and

d. disbursement of information for each QCM/reagent, such as date shipped and received at the Site, quantity, and name of recipient.

4. **VQA WEB SITE**

The Contractor shall maintain and update an interactive internet web site for posting relevant VQA information. Paragraphs A.3.a.1) and D.4, above, provide examples of relevant VQA information to be posted on the web site. See the current VQA web site -- http://aactg.s-3.com/vqa.htm -- for additional examples.

5. **DAIDS-ENTERPRISE SYSTEM INTERFACE**

The Contractor shall provide VQA information, specified by the Project Officer, through the DAIDS-Enterprise System (see APPENDIX C for information on the DAIDS – Enterprise System) including:

a. site and VQA contact information;

b. site certification status and assay capability;

c. assay methodology/protocols; and

d. PT schedules.

6. **ELECTRONIC COMMUNICATION**

The Contractor shall:

a. Provide the capability to receive and transmit data files electronically via the LDMS and to communicate electronically via secure e-mail with all Sites, the Central Database, the DAIDS Enterprise System, and the Project Officer. See Appendix C for a description of databases and software systems.

b. Provide a state-of-the-art software system for data management for expedited processing of selected high-priority information (e.g., randomization assignment, monitoring progress of a particular study, tracking of serious adverse events) and for ready transferal of data and complete system and data documentation to NIAID or others at any point during the contract. The system shall provide sufficient flexibility and accessibility to answer any inquiries in a timely manner, typically no more than one business day.

7. **SYSTEM SECURITY**

The Contractor shall provide security needs to meet NIH requirements. Develop a plan and submit it to DAIDS for Office of Technology and Information Systems (OTIS), NIAID, approval. Implement and maintain security requirements for the computer system used for data management to:

a. ensure patient confidentiality for all subject or donor records (both hard copy and electronic);

b. ensure security of data related to performance evaluation of participating Sites; and

c. provide security against anticipated risks, including loss of confidentiality of subject records and viral or catastrophic loss of study data or important software.

8. **SYSTEM MAINTENANCE AND UPGRADES**

a. The Contractor shall maintain and upgrade software programs that are compatible with current software in use at NIAID and with changes made in NIAID systems. Any computer system for data management or new software must meet OTIS standards and should be developed with the software, Operating System's (OS), languages and tools recommended by OTIS in order to ensure integrated operability with the rest of NIAID's databases and infrastructure. Before any conclusions are made on any software purchase or development, consultation with the Project Officer and OTIS staff, resulting in a decision on direction and the software, OS's, languages and tools to be used, must be completed.

b. Establish reliable and secured electronic communication linkages with NIAID and study site investigators that facilitate sending e-mail and sharing word processor and data files.

c. Management tools, computer systems, databases, documentation, data, and any other electronic files or items developed via this contract will remain the property of the U.S. Government.

9. **INTERACTION WITH OTHER NIAID CONTRACTS**

At the request of the Project Officer, the Contractor shall perform data entry or interact with other NIAID contracts for the exchange of data, movement of samples and investigational products. Contractor may be asked to download or transfer data to other DIADS or DAIDS supported software systems.

10. **INFORMATION TECHNOLOGY (IT) REPORT**

The Contractor shall (with input from NIAID subject matter and OTIS staff) study the Information Technology (IT) hardware; software, networking and security needs for the entire project and develop a report of the IT requirements (including a complete IT security assessment). Part of this process shall include interaction with and review by OTIS staff to ensure alignment with NIAID IT operations, business processes, and documentation deliverables for the proposed IT infrastructure. The study and final recommendations should include: IT architecture (network, security, server, application, and database), schemas, run books, processes, procedures, disaster recovery, failover, troubleshooting, application/system monitoring, change control/management.

11. **INFORMATION SECURITY (INFOSEC)**

InfoSec consists of:

a. Confidentiality -- the prevention of unauthorized disclosure/use of information;

b. Integrity -- the prevention of unauthorized modifications to information; and

c. Availability -- ensuring the reliable and timely access to data or computing resources.

The Contractor shall (with input from NIAID subject matter and OTIS staff) conduct a study of the InfoSec requirements of the entire project including, but not limited to: the privacy requirements of clinical data; physical and electronic security for both hardware, software and communications; the question of whether all participants in the contract (subcontractors, NIAID staff, study site investigators, etc.) need to have a secure capability for communication and exchange of information in the case of a national disaster that may disrupt the ability to interact and exchange needed information. Part of this must include a definition of what the entire system is, such as the physical and logical description of the entire planned system including hardware, software, communications, InfoSec and other considerations.

F. EXPANSION OPTION(S)

The Government anticipates a need to provide the services outlined in this Statement of Work to additional Sites. The base contract covers approximately 80 Sites (55 domestic and 25 international) with an estimated increase through Options to approximately 120 Sites. Over the course of the Contract, the number of Sites is expected to expand to approximately 65 domestic Sites and 55 international Sites. Domestic Sites will be located within the continental United States, Puerto Rico and Hawaii. Most of the international Sites will be located in South America, the Caribbean Islands, Africa, and Asia (22 of 25 current international Sites are located in these areas). A small number of Sites may be located in other areas (currently, one Site is located in Canada, one in Europe and one in Australia). Not all assays will be quality controlled at all Sites. Such an increase in the Contractor's activities may be activated, at the discretion of the Government, as an Option. Each Option will cover the addition of 5 sites; although more than one Option may be executed in any contract year.

1. EXPANSION PLAN

The Contractor shall develop a plan to expand the required staff, facilities and other resources necessary to provide the services called for in the Statement of Work to 5 additional Sites, including the timelines for all tasks involved in implementing the expansion, proposed modifications in organizational structure, management procedures, and other Contractor functions that may be required to carry out such an expansion.

2. PLAN IMPLEMENTATION

Based on the Project Officer recommendation to implement the expansion plan, the Contracting Officer will authorize the exercise of each Option through a Modification to the contract. More than one, but not more than 3, Options may be exercised in a year.

G. TRANSITION PLANS

The Contractor shall exert its best efforts to ensure an orderly and safe assumption of activities from the current contractor and an orderly transition to a possible successor contractor prior to expiration of this contract.

1. ASSUMPTION OF ACTIVITIES FROM THE CURRENT CONTRACTOR

The Contractor shall:

a. Implement its plan including the tasks that are associated with the relocation effort from the current contractor and the manner of operations required by the Contractor during the transition period. This shall include safe and effective coordination with the current contractor at the start of the new Contract period for transfer of Contract-related materials including:

   1) Stored QCMs/reagents. The Contractor shall perform calibration and lot-to-lot comparisons between QCMs/reagents received from the predecessor contractor and any QCMs developed by the Contractor.

   2) All computerized data files and software systems (with documentation and specifications) including proficiency testing and real-time assay validation files, assay development research data files, inventory files, and statistical analysis data files.

   3) Laboratory/manufacturer correspondence files.

   4) Government Furnished Property (GFP). Verification of equipment performance standards shall take place prior to and after the transfer.

b. Coordinate with the Sites to ensure an orderly transition including:

   1) Providing Sites with contact information for the Contractor.

2) Providing Sites with instructions for delivery of assay results to the Contractor and instructions concerning any schedule changes caused by the transition.

3) Providing Sites with information on any changes in the proper use of QCMs, storage of QCMs, assay methods or reporting requirements.

2. **TRANSITION OF ACTIVITIES UPON COMPLETION OF THE CONTRACT**

The Contractor shall:

a. Twelve months prior to the completion of this Contract, submit to the Project Officer a plan that details the transition to a successor Contractor of all Contract-related materials. These materials shall be organized and catalogued in sufficient detail to support an orderly transition to the successor Contractor. The Contractor shall work with the Project Officer and the Contracting Officer to refine and complete this plan and a final plan submitted 6 months prior to the expiration date of the Contract. The plan shall include recommended steps to sustain the activities provided for in the Contract during transition and shall include delivery to the Government or its designee by the expiration date of this Contract all Contract-related items including:

1) Stored QCMs/reagents. The Contractor shall perform calibration and lot-to-lot comparisons between QCMs/reagents received from current Contractor and any QCMs developed by the successful offeror.

2) All computerized data files and software systems (with documentation and specifications) including systems for tracking proficiency testing and real-time assay validation data, assay development research data, inventory data, and statistical analysis data.

3) Laboratory/manufacturer correspondence files.

4) Government Furnished Property (GFP). Verification of equipment performance standards shall take place prior to the transfer.

b. Notify all Sites as early as possible of the transition and provide to the Sites schedules for the transition and instructions concerning any changes in testing schedules anticipated during the transition.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.. DELIVERIES of this contract:

The Contractor shall provide the reports and deliverables specified below. All reports shall be submitted in electronic form as PC-formatted computer files in Microsoft Word™ and Microsoft Excel™ and/or searchable PDF format. Electronic versions shall be sent on CD or more current electronic data storage medium, by U.S. mail or courier service. All reports shall be archived on CD or other appropriate media for surrender to the Government at the expiration of the Contract.

A. Site-Specific Assessment Reports

The Contractor shall submit to the Project Officer and to the relevant Sites a copy of Site-specific assessment reports as follows:

1. Provide, via electronic mail, each Site with its own Site-specific preliminary report of the Proficiency Testing results (provisional performance status) five working days following data receipt from all participating Sites. Upon final determination of Site performance status, a report shall be submitted to the Sites, the Project Officer and others, as requested by the Project Officer.

2. Within 5 working days of evaluation of real-time assay performance results, provide each Site, via electronic mail, with a preliminary Site-specific report of the results. Upon final determination of Site performance status, a report shall be submitted to the Sites, the Project Officer and others, as requested by the Project Officer.

B. Virologic Assay Research and Development Reports

The Contractor shall submit written reports (either electronic or hard copies) of all research and development studies performed as specified in Paragraph B of the Statement of Work as follows:

1. Within 10 working days following completion of data analysis, assay study results shall be reported to the Project Officer and relevant User Group(s) as specified by the Project Officer.

2. Within 3 months of study completion, the Contractor shall submit to the Project Officer materials to support preparation of scientific manuscripts for publication in peer reviewed journals. Prior to submission for publication, all manuscripts shall be submitted in hard copy or electronic copy to the Project Officer and others, as specified by the Project Officer.

C. Quarterly Progress Reports

The Contractor shall submit copies of Quarterly Progress Reports on/before the 15th of the month following the end of each quarter. A Quarterly Progress Report shall not be required when submitting an Annual or the Final Report. Each report shall consist of:

1. A cover page containing:

   a. Contract number and title
   b. Period of performance being reported
   c. Type of report and period covered
   d. Contractor's name and address
   e. Author(s)
   f. Date of submission

2. An introduction, covering the purpose and scope of the Contract effort pertaining to the period of the report.

3. Summaries or computer printouts of activities as specified in the SOW:

    a. Performance Evaluation Report [Proficiency Testing (PT) and Real-time Assay Validation]. For each assay system tested at the Sites the following information shall be included:

        1) Quality Control Materials (QCMs) acquisition, characterization and distribution, including type, source, amount, characterization data, storage and inventory information, receiving Sites and relevant dates
        2) Analysis of results, noting the statistical methodologies employed
        3) Performance status of Sites including criteria for successful performance
        4) Summary of problems, corrective actions and subsequent performance

    b. Research and development of virologic methodologies. For each new assay evaluation, kit/reagent evaluation, methodologies comparison and assessment of assay parameters, the following shall be included:

        1) Study objectives
        2) QCMs/kit acquisition, characterization and distribution, including type, source, amount, characterization data, storage and inventory information, receiving Sites and relevant dates
        3) Sites participating in studies
        4) Analysis of results
        5) Problems encountered and solutions employed
        6) Recommendations based on research results

    c. Research on biostatistical methodologies. This shall include objectives, results and recommendations for application.

    d. Scientific Activities. This shall include any research not included in paragraphs a., b. and c., above; a list of scientific meetings and conferences attended; a list of manuscripts published, submitted or in preparation; and a list of abstracts submitted for presentation or in preparation.

4. Summary of facilities/equipment issues

5. Summary of data management issues which shall include problems and solutions related to computer hardware and software

6. Summary of Site-specific issues which shall include difficulties and solutions related to material send-outs and transmission of QC data from the Sites

7. Summary of meetings/discussions with the Project Officer regarding issues relevant to the conduct of the contracted work

8. Personnel Report, which shall include name, title, percent effort and responsibility of each individual that is working on the Contract

D. Annual Progress Reports

Annual Reports shall include the last Quarterly Progress Report and an Annual Table of Contents referring to previous Quarterly Progress Reports. Annual Reports shall be submitted on or before the 30th of the month after each anniversary date of the Contract. An Annual Report is not required for the period when the Final Report is due.

E. Final Progress Report and Summary of Salient Results

The Final Report shall cover the entire Contract performance period and be in sufficient detail to explain comprehensively the accomplished tasks, a brief description of any unfinished projects, and a status report on transition or shut down activities. In addition, the Contractor will provide a 200 word "Summary of Salient Results" detailing the important accomplishments from the contract studies during the performance of the contract. The Final Report shall be submitted on or before completion of the Contract.

F. Other Deliverables

1. Transition plans: Within 10 business days of the start of the Contract, the Contractor shall provide a transition plan that describes procedures for the safe and orderly relocation of all VQA-related materials from the current Contractor, as outlined in Paragraph G of the SOW. This plan shall include staffing requirements and a description of work during the transition.

2. Twelve months prior to the expiration date of the Contract, the Contractor shall provide a draft transition plan which describes proposed procedures for an orderly transition to a subsequent Contractor or the Government, and estimated cost as outlined in Section G of the SOW.

3. A final transition plan shall be provided six months prior to the completion date of the Contract.

4. Contract Completion: The Contractor, subject to DAIDS Project Officer approval, shall deliver to the Government or its designee, by the completion date of this Contract, stored QCMs and reagents, inventory and software systems including software programs, labeled and inventoried paper files, and Government Furnished Property (GFP), as outlined in Paragraph G. of the SOW.

G. **REPORT DISTRIBUTION**

Type of Report	No. of Copies	Due Date
Site-specific Assessment Reports	1 copy – Each Site 1 copy – PO	Due within 5 working days of PT data receipt or real-time assay evaluation.
Virologic Assay Research and Development Reports	1 copy – PO 1 copy – User Groups	Due within 10 working days of completion of data analysis.
Quarterly Report	Original –CO 1 copy – PO	Due on/before the 15th of the month following each quarterly reporting period. Not due when Annual or Final Reports are due.
Annual Report	Original –CO 1 copy – PO	Due on/before the 30th of the month after each Anniversary date of the contract. Not due when the Final Report is due.
Final Report and Summary of Salient Results	Original –CO 1 copy – PO	On/before the completion date of the contract.
Transition Plan (Contract start-up)	Original – CO 1 copy – PO	10 business days after the effective date of the contract.
Transition Plan (Draft)	Original –CO 1 copy – PO	Twelve months prior to completion of the Contract.
Transition Plan (Final)	Original –CO 1 copy – PO	Six months prior to completion of the Contract.

If the Contractor becomes unable to deliver the reports specified hereunder 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 written notice at least 10 business days prior to the due date of anticipated delays with reasons therefore. The Contracting Officer and Project Officer must approve the extension in writing. A new delivery date must be established.

H. Addressees:

Project Officer: National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Division of AIDS, DDCSB
6700-B Rockledge Drive, Room 5208, MSC 7624
Bethesda, MD 20892-7624

Contracting Officer: National Institutes of Health, DHHS
National Institute of Allergy and InfectiousDiseases
Contract Management Program, DEA
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.

ITEM 13: FAR Clause **52.232-20, Limitation of Cost**, is deleted in its entirety and FAR Clause **52.232-22, Limitation of Funds** (APRIL 1984) is substituted therefor. [Note: When this contract is fully funded, FAR Clause **52.232-22, Limitation of Funds** will no longer apply and FAR Clause **52.232-20, Limitation of Cost** will become applicable.]

No additional or supplemental Authorized Substitutions of Clauses are applicable to this solicitation. 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 30: FAR Clause **52.217-6, Option for Increased Quantity** (MARCH 1989), is applicable to this solicitation.

ITEM 39: FAR Clause **52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns** (JUNE 2003), is applicable to this solicitation.

ITEM 50: FAR Clause **52.227-14, Rights in Data--General** (JUNE 1987).

No additional or supplemental Additional Contract Clauses are 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:

ITEM 85: FAR Clause **52.244-6, Subcontracts for Commercial Items** (JULY 2004)

No additional or supplemental Additional FAR Contract Clauses Included in Full Text are applicable to this solicitation. 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 (see page 23)

HOW TO PREPARE AN ELECTRONIC PROPOSAL (see page 24)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: December 15, 2004] (see page 26)

[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**
- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration** [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]
- **Government Notice for Handling Proposals**
- **Targeted/Planned Enrollment Table**
- **Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement**

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

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

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **Inclusion Enrollment Report**
- **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)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule ___**
- **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 page limitation of 100 pages.	N/A
Business Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Ten (10) bound copies.	Limited to not-to-exceed 150 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 contain electronic versions of all proposal information (both technical and business – clearly marked). 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)	

TECHNICAL PROPOSAL PAGE LIMITS INCLUDE: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc..
TOTAL PAGE COUNT DOES NOT INCLUDE: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.
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 PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

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 Box 18 of the RFP cover page and must be received on/before the closing date and time.

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.
- Pages printed front-to-back will count as 2 pages.
- 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-DAIDS-05-16
RFP Title: "DAIDS Virology Quality Assurance"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by December 15, 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: Lola Kellum
RFP-NIH-NIAID-DAIDS-05-16
FAX# (301) 402-0972
Email : kelluml@niaid.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 10: **THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS.** However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

ITEM 11: In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of *[percentage to be identified in the specific RFP]* percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

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 August 15, 2005.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with Options, with a period of performance of seven (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 10.5 full time equivalents (FTEs) for the base period. 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 cost 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 20: SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (*Complete address and contact information can be found on the SECTION A SOLICITATION/CONTRACT FORM cover page, Blocks 9 & 15, of the specific RFP*) by obtaining written and dated acknowledgment of receipt from:

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

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 30: Sharing Research Data, is applicable to this solicitation.

ITEM 31: Sharing of Model Organisms for Biomedical Research, is applicable to this solicitation.

ITEM 32: Specific Copyright Provisions Applicable to Software Development and/or Enhancements, is applicable to this solicitation.

ITEM 34: Small Business Subcontracting Plan, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation. The anticipated minimum subcontracting goals for this RFP are as follows:

- 23% for Small Business
- 5% for Small Disadvantaged Business
- 3% for Women-Owned Small Business
- 5% for HUBZone Small Business
- 3% for Veteran-Owned Small Business
- 3% Service-Disabled Veteran-Owned Small Business.

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

ITEM 37: Salary Rate Limitation in Fiscal Year 2005, will be applicable to this solicitation.

ITEM 40: 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 three (3) contracts completed during the past three years and the last three (3) contracts awarded currently in process that are similar in nature to the solicitation workscope.

ITEM 48: Electronic and Information Technology Accessibility, is applicable to this solicitation.

ITEM 49: **Prohibition on Contractor Involvement with Terrorist Activities**, is applicable to this solicitation.

ITEM 50: **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 52: **Project Objectives, NIH-1688-1, is** applicable to this solicitation.

ITEM 54: **Human Subjects**, is applicable to this solicitation.

ITEM 55: **Information Technology Systems Security**, is applicable to this solicitation.

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 57: **Proposal Cover Sheet,** is applicable to this solicitation.

ITEM 60: **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 61: **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 66: **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/price, past performance and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance 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(s) 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. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by Institute that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health,;or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.
Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. **EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

** (Note to Contracting Officers: The plan or documentation as to the rationale for not providing a plan shall be evaluated by program staff and shall not be scored. However, weaknesses in a plan or in the rationale for not permitting the sharing of research data may be part of discussions.) **

5. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of 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.

6. **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.

7. **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.

OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO APPENDIX A – Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATON RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

CRITERA	**WEIGHT**
A. **TECHNICAL APPROACH**	**60 points**

Understanding of the requirements as evidenced by the Offeror's proposed technical plan to perform the following functions:

1. Proficiency Testing, Real-Time Assay Validation and Assay Research and Development (30 points)

   a) Maintaining virology laboratory performance standards for specific assays conducted at remote Sites, through a proficiency testing program and a real time assay validation program. Providing Sites with necessary QCMs and instructions, obtaining and analyzing results from the Sites, monitoring site performance and providing training as required.

   b) Evaluating new and existing virologic and analytic methodologies and their application to clinical studies. Facilitating multi-site investigations of new technologies, comparisons of existing technologies and reagents and evaluations of handling and storage conditions on assay results. Analyzing results and developing appropriate analytical methodologies and quality control parameters.

2. Acquisition and Maintenance of QCMs / Information Dissemination (30 points)

   a. Obtaining, characterizing and distributing QCMs to multiple Sites, domestic and international. Development of a volunteer donor program for obtaining materials from human subjects. Storage and cataloguing of QCMs

b. Disseminating quality assessment technical and scientific data through publications and presentations. Developing consensus protocols, maintaining a web site for posting relevant information, preparing training materials, providing expert advice, conducting training and participating in conference calls and meetings

c. Maintaining and updating computerized inventory and database systems to support the acquisition, testing, storing and disbursement of QCMs. Providing for the security of all data and programs. Ensuring safe and orderly transition of all materials and data to a successor at the end of the Contract.

B. P**ERSONNEL QUALIFICATIONS** **30 points**

1. Principal Investigator (key personnel): (10 Points)

Documented evidence of related experience in the principles and practices of virology quality assessment for HIV and HIV-associated viral co-pathogens; evidence for ability to hire staff for projects in a way that reflects flexibility and responsiveness to changing needs

2. Project Manager (key personnel): (10 Points)

Documented evidence of the relevance and extent of related experience with efficiently managing and coordinating multi-task projects, customer service and laboratory trouble shooting.

3. Other Personnel/Staffing Plan: (10 Points)

a. Relevance and extent of experience of other professional and research technical and support staff in the area of virologic methodologies (e.g. RNA quantification, quantitative cultures, DNA PCR, drug susceptibility assays) and in statistical modeling and software system management; logistical adequacy of the staffing plan for the conduct of the project including the time commitment of the professional and technical staff

b. Staffing plan for the conduct of the project, including appropriateness of the time commitments of all staff, the clarity and appropriateness of assigned roles, and lines of authority.

c. Adequacy of the administrative and organization framework, with lines of authority and responsibility clearly demonstrated, and adequacy of the work plan, with proposed time schedule for achieving contract objectives and maintaining quality control over the implementation and operation of the project. Adequacy of back-up staffing and the evidence that they will be able to function as a team.

C. **FACILITIES AND RESOURCES** **10 points**

Documented availability of facilities, equipment, and resources necessary for this project and documented facility security and emergency back-up measures. Plan for compliance with all safety guidelines and regulations including training and monitoring of personnel for exposure to infectious and hazardous reagents. The Offeror shall provide a detailed floor plan indicating where work will be performed and a list of equipment dedicated to the project.

BASE PERIOD TOTAL: 100 points

D. **OPTION TO EXPAND** **25 points**

Demonstrated ability of the Principal Investigator and the Project Manager to oversee and manage the expansion; ability to recruit qualified personnel in a timely manner; adequacy of the resources and facilities to address expansion needs

BASE PERIOD + OPTION TOTAL: 125 points

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS and FORMAT for: DAIDS Virology Quality Assurance
TECHNICAL PROPOSAL – TABLE OF CONTENTS

THE BELOW TEMPLATE MUST BE USED AS THE TABLE OF CONTENTS FOR YOUR TECHNICAL PROPOSAL AND ALL INFORMATION IN YOUR TECHNICAL PROPOSAL SHOULD BE PRESENTED IN THE ORDER SPECIFIED BELOW.

YOU ARE REMINDED THAT THE TOTAL PAGE LIMITATION FOR THE ENTIRE TECHNICAL PROPOSAL PACKAGE IS 100 PAGES. PLEASE REFER TO PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL FOR SPECIFIC PROPOSAL PREPARATION INSTRUCTIONS REGARDING PAGE LIMITATIONS

THESE ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS REFLECT THE REQUIREMENTS OF THE RFP AND ARE MEANT TO PROVIDE A CLEAR UNDERSTANDING OF THE INTENT OF THIS SOLICITATION.

OFFERORS ARE ADVISED TO GIVE CAREFUL CONSIDERATION TO THE STATEMENT OF WORK, ALL REFERENCE MATERIAL PROVIDED AS APPENDICES AND ATTACHMENTS, AND THE TECHNICAL EVALUATION CRITERIA IN THE DEVELOPMENT OF YOUR PROPOSAL.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1. TECHNICAL APPROACH – STATEMENT OF WORK

A IMPLEMENTATION OF VIROLOGY SITE PERFORMANCE STANDARDS AND SITE ASSESSMENT

1. PROFICIENCY TESTING

Discuss your plan for providing Sites with QCMs listed in the SOW, providing Sites with instructions regarding the QCMs, retrieving and analyzing PT data and reporting results.

2. REAL-TIME ASSAY VALIDATION

Discuss your plan for providing Sites with the QCMs listed in the SOW for real-time assay validation and providing Sites with instructions regarding the QCMs.

3. SITE ASSISTANCE AND TRAINING

Discuss your plan for providing training to Site personnel as stated in the SOW and for providing assistance to Sites whose results deviate from accepted values agreed upon by the Contractor, User Groups and the Project Officer. Include plans for re-testing sites after implementation of corrective action.

B. ADAPTATION, STANDARDIZATION AND APPLICATION OF VIROLOGIC AND BIOSTATISTICAL ANALYTICAL METHODOLOGIES

1. VIROLOGIC ASSAY METHODOLOGIES

Discuss your ability to perform multi-Site evaluations of new and existing virologic assays; perform multi-site comparisons of commercial or specific laboratory-based assays, assay kits or reagents; and perform multi-site evaluations and comparisons of specimen handling, processing, and storage procedures. Discuss plans to provide QCM materials necessary for the evaluations, collect data from the Sites and analyze data.

2. ANALYTICAL AND BIOSTATISTICAL METHODOLOGIES

Discuss your ability to evaluate and apply existing or novel statistical models for assessment, interpretation, and validation of virologic assay test results and for implementation of quality control parameters.

C. PROVISION OF QUALITY CONTROL MATERIALS/REAGENTS

1. DONOR PROGRAM

Discuss plans for development of a donor program for obtaining materials from well-characterized human subjects. Discuss access to populations of infected donors and discuss plans for acquisition of materials from volunteer donors infected with each known subtype of HIV and relevant subtypes of other viruses. Include plans for compliance with applicable domestic and international regulations on the use of human subjects i (e.g. IRB submission and approval plans, consent procedures, etc.) and with HIPAA and Privacy Act requirements in Section 2 below. You are reminded that NIH regulations do not permit contract funds to be expended on customs payments to foreign governments. It will be desirable for foreign offerors to provide a letter from their government agreeing to permit duty-free shipment.

2. ADDITIONAL QCMs/REAGENTS

Discuss your plans for the acquisition of additional QCMs and reagents including materials derived from HIV-infected cell cultures (e.g. infected cell lines, viral lysates, viral stocks, enzymes). Document your ability to work with biohazardous materials, especially bloodborne pathogens (HIV, HCV, etc.).

3. CHARCTERIZATION OF QCMs

Discuss your ability to determine QCM and reagent characteristics (HIV RNA quantification, p24 measurement, etc.), and their optimal use and storage conditions.

4 STORAGE OF QCMs

Discuss your ability to securely store QCMs, discuss both primary and backup systems.

5. QCMs/REAGENT SHIPPING

Discuss plans to ship QCMs/reagents to specified domestic and international destinations under appropriate shipping conditions (e.g. temperature monitoring) and in accordance with IATA/ICAO dangerous goods shipping regulations and other relevant shipping regulations. Include in the Technical Proposal documentation of required licenses and permits, or include plans to obtain them prior to Contract award date.

6. SAFETY AND HEALTH

Discuss plans for the safe handling of potentially hazardous biological specimens, in particular bloodborne pathogens such as HIV, HCV, etc. Include plans for training of site personnel in the handling of biohazardous materials.

7. FACILITIES

Discuss facilities available for the VQA program, include security and backup measures. Discuss availablility of biosafety level 2/3 or 3 laboratory for culturing HIV.

8. QCM/REAGENT DOCUMENTATION

Discuss plans for record keeping and documentation for all QCMs and reagents.

D. DISSEMINATION OF VIROLOGY QUALITY ASSESSMENT (VQA) TECHNICAL AND SCIENTIFIC DATA

1. PUBLICATION AND PRESENTATION OF DATA

Discuss your ability to prepare manuscripts for publication in peer reviewed journals and to prepare and present data at national and international meetings. Discuss your ability to develop and distribute protocols for virologic assays via hard copy, electronic mail and web site.

2. CONFERENCE CALLS AND MEETINGS

Discuss plans to communicate with the Project Officer, Sites, User Groups and others specified by the Project Officer through conference calls and meetings. Indicate personnel to be included in regularly scheduled conference calls and personnel to be included in regularly scheduled meetings with the Project Officer.

E. COMPUTERIZED SOFTWARE SYSTEMS

1. PT AND REAL-TIME ASSAY VALIDATION DATA TRACKING SYSTEM

Discuss plans to provide a software system(s) to track data relating to PT and real-time assay validation as stated in the SOW.

2. ASSAY RESEARCH AND DEVELOPMENT DATA SYSTEMS

Discuss plans to provide software systems that support virologic assay research and development activities (Paragraph B.1., of the SOW) including software systems that support biostatistical analyses (Paragraph B.2., of the SOW). Include plans to design any software used to capture or analyze data in a format that will easily permit further development and inclusion in the LDMS, should the assays be implemented in clinical trials and performed on patient specimens.

3 QCM DATA TRACKING SYSTEM

Discuss plans to provide a computerized software system that tracks QCM data including the donor program. Provide details of compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.) and with HIPAA and Privacy Act requirements in SECTION 2., below.

4. VQA WEB SITE

Discuss plans to maintain and update an interactive internet web site for posting relevant VQA information.

5. DAIDS-ENTERPRISE SYSTEM INTERFACE

Discuss plans for interface with the DAIDS-Enterprise System (see APPENDIX C for information on the DAIDS – Enterprise System) for transfer of data specified in the SOW.

6. ELECTRONIC COMMUNICATION

Discuss your plans to receive and transmit data files electronically via the LDMS and to communicate electronically via secure email with all Sites, the Central Database, the DAIDS Enterprise System, and the Project Officer. See Appendix C for a description of databases and software systems. Include plans for ready transferal of data and complete system and data documentation to NIAID or others at any point during the contract.

7. SYSTEM SECURITY

Discuss plans to provide for security needs to meet NIH requirements. The successful offeror will be required to develop a plan and submit it to DAIDS for Office of Technology and Information Systems (OTIS), NIAID approval as specified in the SOW.

8. SYSTEM MAINTENANCE AND UPGRADES

Discuss plans to maintain and upgrade software programs that are compatible with current software in use at NIAID and with changes made in NIAID systems.

Establish reliable and secured electronic communication linkages with NIAID and study site investigators that facilitate sending e-mail and sharing word processor and data files.

Management tools, computer systems, databases, documentation, data, and any other electronic files or items developed via this contract will remain the property of the U.S. Government.

9. INTERACTION WITH OTHER NIAID CONTRACTS

Discuss plans for interaction with other NIAID contracts for the exchange of data.

10. IT REPORT

Discuss you ability to develop a report of the IT requirements (including a complete IT security assessment) including personnel who will interact with NIAID OTIS staff.

11. INFORMATION SECUTRITY (INFOSEC)

Discuss plans to conduct a study of the InfoSec requirements of the entire project including, but not limited to: the privacy requirements of clinical data; physical and electronic security for both hardware, software and communications; the question of whether all participants in the contract (subcontractors, NIAID staff, study site investigators, etc.) need to have a secure capability for communication and exchange of information in the case of a national disaster that may disrupt the ability to interact and exchange needed information.

F. EXPANSION OPTION(S)

1. EXPANSION PLAN

Offerors' proposal for Options shall address the approach for adding up to three (3) Options per year, each option including five (5) additional Sites. Discuss the ability of the Principal Investigator and Project Manager to oversee and manage the expansion. Discuss plans to expand the required staff, facilities and other resources necessary to provide the services called for in the Statement of Work to provide additional domestic and international Sites, including the timelines for all tasks involved in implementing the expansion, proposed modifications in organizational structure, management procedures, and other Contractor functions that may be required to carry out such an expansion.

2. PLAN IMPLEMENTATION

Based on the Project Officer recommendation to implement the expansion plan, the Contracting Officer will authorize the exercise of each Option through a Modification to the contract. More than one (1), but not more than three (3), Options may be exercised in one year.

G. TRANSITION PLANS

1. ASSUMPTION OF ACTIVITIES FROM THE CURRENT CONTRACTOR

Describe your plan for transition of the current program from the incumbent including acquisition of QCMs, all government furnished property and all data and data systems. Describe plans for characterizing QCMs acquired from the incumbent. Include plans for coordinating with Sites for transition of the VQA program. Provide timelines for the transition.

2. TRANSITION OF ACTIVITIES UPON COMPLETION OF THE CONTRACT

Describe general plans for transition of the program to another Offeror at the end of the Contract. A specific draft plan will be required 12 months prior to the expiration date of the Contract and a final plan will be required 6 months prior to the expiration date.

SECTION 2. HUMAN SUBJECTS ASSURANCE, HIPAA, PRIVACY ACT AND ANIMAL ASSURANCE

A. HUMAN SUBJECTS ASSURANCE

Include plans for compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.).

B. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Include plans for compliance with HIPAA.

C. PRIVACY ACT

Include plans for compliance with the Privacy Act.

SECTION 3. DATA SHARING PLAN

SECTION 4. PERSONNEL/STAFFING

A. KEY PERSONNEL

Several high-level or Key Personnel will be required for this contract.

Describe the experience and qualifications, as well as the percentage of the total time each will be committed to the project. Identify the composition of the task or work group, its general qualifications and recent experience with similar efforts. As a minimum, this effort will require different staff/areas of expertise at different times over the course of the contract. Please provide documentation to describe:

- Key Personnel (limit CVs to 2-3 pages)
- Qualifications and experience as supported by academic degree(s) and expertise (refer to Technical Evaluation Criterion B.
- Availability for the proposed project.
- Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to successfully manage the Project as demonstrated by the management plan and previous relevant experience.

B. OTHER PERSONNEL

Offeror(s) should discuss the related experience and the role of other personnel. Provision of curriculum vitae(s) is not required in the Technical Proposal but may be included in the Business Proposal. (Refer to Technical Evaluation Criterion B.)

C. STAFFING PLAN

Discuss the logistical adequacy of the staffing plan for the conduct of the project including the time commitment of the professional and technical staff.

SECTION 5. FACILITIES AND RESOURCES

Discuss the availability of facilities, equipment and resources necessary for this project. Include a plan for compliance with safety guidelines and regulations. Include the floor plan of the proposed facility and list equipment and resources dedicated to the project. Offerors should provide a copy of any lease agreements for space and address the availability of the facility at the time of award. Include information on any renovations that may be necessary prior to start-up. It is estimated that 40 cu.ft. of -80°C space, 60 cu.ft. of -30°C space, 80 cu. ft. of 4°C space, and one liquid nitrogen tank will be required to store QCMs. A list of Government-supplied equipment is provided as APPENDIX E.

SECTION 6. OTHER INFORMATION

APPENDIX B
ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
UNIFORM BUDGET ASSUMPTIONS

1. For costing Proficiency Testing (PT) and real-time assay validation, please assume shipment of: four, 10 ml whole blood samples in Acid Citrate Dextrose (ACD) to 60 Sites 2 times/yr; eight, 5 ml whole blood samples in ACD to 40 Sites, 2 times/yr; five, 5 ml whole blood samples in ACD to 60 Sites, 2 times/yr; three, 5 ml vials of 400 pg/ml concentrated HIV viral lysate and a 50 ml bottle of diluent to 50 Sites 3 times/yr; fifteen, 0.5 - 1.25 ml spiked plasma samples (varying HIV RNA copies/ml) to 80 Sites 3 times/yr; sets of 100 cell pellets containing either 0 or 10 HIV DNA copies to 50 Sites 2 times/yr. Approximately one-third of the shipments will be made to international Sites located in the Caribbean, Africa, Asia and South America.

2. For costing data analyses, please assume collection of PT data for each assay 3 times/year for 60 Sites. Assays for PT currently include HIV DNA PCR, HIV RNA Viral Load, HIV Culture and HIV Drug Resistance Genotyping. Up to 4 additional assays per year may be added for PT.

3. For costing training to Sites, please assume conducting 2 training workshops, each of 2 days duration, per year at the Contractor's site, with up to 10 participants per workshop. Contractor will not be responsible for participant travel support.

4. For costing assistance to Sites, assume 2, five day visits of international Site personnel (1 person from each of 10 Sites) to the Contractor and 2, five day visits of 2 Contractor personnel to international Sites per year. Contractor will not be responsible for Site personnel travel support.

5. Please assume evaluation of up to four existing or newly developed virologic assays per year. For each evaluation assume provision of assay-appropriate known standards and coded QCMs to up to ten selected Sites, collection of data from the sites and data analysis.

6. Assume comparisons of up to four commercial or specific laboratory-based assays, assay kits or reagents. For each comparison, assume provision of appropriate known standards and coded QCMs to up to ten selected Sites, collection of data from the sites and data analysis.

7. Assume up to four evaluations and comparisons of specimen handling, processing, and storage procedures. For each evaluation/comparison, assume provision of appropriate known standards and coded QCMs to up to 10 selected Sites, collection of data from the sites and data analysis.

8. It is estimated that statistical analysis of QC data and development/application of analytical methodologies will require a Ph.D. level statistician at 60% effort and B.S. level programmers at 120% effort.

9. For costing purposes, please assume 2 visits/yr of 2 Contractor personnel, each lasting 3 days, to Bethesda, Maryland to meet with the Project Officer and to attend DAIDS-sponsored meetings. Also, please assume travel for 2 Contractor personnel for presentation of data at 2 domestic meetings and 1 international meeting each of 5 days duration, per year. For costing purposes, please assume one two-day site visit per year of the Project Officer to the Contractor's site.

10. It is estimated that 40 cu.ft. of -80°C space, 60 cu.ft. of -30°C space, 80 cu. ft. of 4°C space, and one liquid nitrogen tank will be required to store QCMs. A list of Government-supplied equipment is provided as an APPENDIX E.

11. Assume the following minimum requirements for hardware and software to be provided by the Contractor:

    a) IBM Compatible computer (PC), with a processor speed of 2 GHz, 512 MB RAM, CD R/W drive, 3.5 floppy drive, 40 GB hard drive, 1600 x 1200 – 16 bit color (8 meg) PCI or AGP, 19" CRT or 17" flat screen monitor, 10/100 Mbps Ethernet card, 4 USB ports
    b) Hewlett Packard (HP) Compatible Laser Jet Printer or other laser printer
    c) Internet service provider and high speed connection to the internet (cable modem, DSL, ISDN, Ethernet)
    d) Software packages, which include Microsoft Windows 2000 or XP, Microsoft Office Suite, Symantec PC Anywhere-Version 10.5 or higher, Backup Software (e.g. Colorado Backup or Iomega), anti-virus software with up-to-date virus definitions (e.g. McAfee or Norton Anti-virus)

APPENDIX C
COMPUTER SYSTEMS

Central Database and LDMS

Most, but not all, Sites are currently linked through an electronic network which is used to transmit virology data from the Sites to a remote Central Database. Sites are also using a customized laboratory data management system (LDMS) that tracks specimens, provides assay templates, calculates derived quantities, produces reports, and generates data files for export from the Site.

Both the Central Database and the LDMS are maintained and updated by the Frontier Science Foundation (www.fstrf.org). Virology data acquired by the Sites for the VQA program are currently exported from the Sites either directly to the current Contractor or it's subcontractor, or to the Central Database. If the data are exported to the Central Database, the Contractor must access and retrieve the data from the Central Database for analysis. The successful offeror or it's subcontractor will require the ability to access VQA data from the Central Database and will require the ability to develop and maintain, in cooperation with Frontier Science Foundation, an interface for such access.

The LDMS will be provided to the successful offeror. Minimum requirements for hardware and software to be provided by the Contractor include:

a. IBM Compatible computer (PC), with a processor speed of 2 GHz, 512 MB RAM, CD R/W drive, 3.5 floppy drive, 40 GB hard drive, 1600 x 1200 – 16 bit color (8 meg) PCI or AGP, 19" CRT or 17" flat screen monitor, 10/100 Mbps Ethernet card, 4 USB ports
b. Hewlett Packard (HP) Compatible Laser Jet Printer or other laser printer
c. Internet service provider and high speed connection to the internet (cable modem, DSL, ISDN, Ethernet)
d. Software packages, which include Microsoft Windows 2000 or XP, Microsoft Office Suite, Symantec PC Anywhere-Version 10.5 or higher, Backup Software (e.g. Colorado Backup or Iomega), anti-virus software with up-to-date virus definitions (e.g. McAfee or Norton Anti-virus)
e. Statistical analysis software package (e.g. SAS)

Division of AIDS – Enterprise System (DAIDS-ES)

The successful offeror will be required to provide some VQA-related information through the DAIDS-ES. While some of this may be accomplished through a link from DAIDS-ES to the VQA web site, some data may need to be shared by the VQA, with DAIDS ES, in which case data sharing agreements, standards, etc. will be required.

The DAIDS Enterprise System (DAIDS-ES) is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. The current components of the DAIDS-ES include:

DAIDS Training Calendar
The DAIDS Training Calendar is an integrated MS-Outlook application to track DAIDS training events. The DAIDS Training Calendar has been developed in response to a need for an easy-to-use system to track and share information about training activities, including content, schedule, participants, travel requirements, registration policies, costs, etc. The system is anticipated in the third quarter of FY 2004.

DAIDS Master Contact System
The DAIDS Master Contact System is a centralized system for all address and contact information for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc. The system is anticipated in the first quarter of FY 2005.

DAIDS Expedited Adverse Event Reporting System (DAERS)
The DAERS is a web-based application for expedited reporting of adverse events in DAIDS sponsored clinical trials. DAERS is a 21 CFR Part 11 compliant system for use in therapeutic, vaccine and prevention trials. The system is anticipated in the third quarter of FY 2005.

DAIDS Protocol Management System

The DAIDS Protocol Management System supports end-to-end clinical trials processes, including: protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and closeout. The system is CDISC and HL7 compliant with full auditing capabilities. The system is anticipated in the fourth quarter of FY 2005.

Successful offerors will be required to interface, integrate or adapt their information system(s) to interact with these and future components of the DAIDS-ES as necessary.

To achieve compatibility, DAIDS and its collaborators (contractors, cooperative agreement holders, grantees, etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis.

This requirement will include the need to utilize DAIDS-ES specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant applications that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES.

Depending upon the architecture and implementation of offerors data management system(s), the following activities may be required to be compatible with the DAIDS-ES:

Build Interface:
Using DAIDS-ES specified data standards, collaborators shall provide access to data in their local system(s). Standards shall either be industry data exchange standards such as those specified by NIH, CDISC, HL7 or adapted versions of these as defined by DAIDS.

System Adaptation:
Collaborators may need to adapt or modify their data management system(s) to receive and store data from the DAIDS-ES. For example, DAIDS is establishing a standardized naming and numbering convention for its awardee institutions. The DAIDS shall provide collaborators with a single set of institution or laboratory names and identifiers for all of its research participants. Collaborator's data system(s) may have to be adapted or modified to accommodate the DAIDS standard(s).

System Integration:
Collaborators may be required to dynamically obtain data from the DAIDS-ES to perform specific job functions. This will require the integration of collaborator's system(s) with the DAIDS-ES via data linkages using the appropriate latency factor or through Web Services. For example, the DAIDS-ES will serve as the central repository for investigator and protocol status information. Collaborator's whose work requires information from the DAIDS-ES must dynamically integrate it into their respective data system(s).

APPENDIX D

SITE LOCATIONS

International Site Locations

City	Country
Sydney	Australia
Gaborone	Botswana
Sao Paulo	Brazil
Rio de Janeiro	Brazil
Toronto	Canada
Beijing	China
Santo Domingo	Dominican Republic
Port-au-Prince	Haiti
Chennai	India
Pune	India
Blantyre	Malawi
Lilongwe	Malawi
Lima	Peru
St. Petersburg	Russia
Dakar	Senegal
Capetown	South Africa
Durban	South Africa
Johannesburg	South Africa
Dar es Salaam	Tanzania
Chiang Mai	Thailand
Bangkok	Thailand
Kampala	Uganda
Trinidad	West Indies
Jamaica	West Indies
Herare	Zimbabwe

APPENDIX E
GOVERNMENT FURNISHED PROPERTY

1. EQUIPMENT

	Description	MFR.	Model	Serial No.	Gov. ID No.	Date Purchased
1	DAI Scientific 17K Liquid Nitrogen Freezer with Controller and Accessories	Taylor-Wharton	17KCT	568009J8	01096328	Nov-93
2	DAI Scientific 7009 Electronic Control Rate Freezer	Gordinier	7009-8750	05044-1293	01096329	Dec-93
3	Curtin Matheson Scientific 3000I Refrigerated Centrifuge and Accessories	Mistral	3000I	SG9204423	01096330	Nov-93
4	Intermec Bar Code Read/Write System	Intermec Corp	9720	9720D01	01188387	Nov-93
5	Intermec Scanner	Intermec Corp	1545	93110501189		Nov-93
6	Intermec Printer	Intermec Corp	4100	93110500633		Nov-93
7	GenProbe Luminometer	GenProbe	Leader 50	120811	01188389	Nov-93
8	Heraeus Centrifuge	Heraeus	3621	193206	00898984	Nov-93
9	Multiscan Microplate	Titertek	347	34706-094	01188390	Nov-93
10	Microplate Washer	Titertek	78-432 00	2362	01188391	Nov-93
11	MVE Cryogenics LN2 Freezer	MVE	XLC-500	JSA93D109	01188392	Nov-93
12	SSBA II Cryosafe/SSBA Class Liquid Nitrogen Tank	Cryosafe	SSBA II	555009M996	01264004	Oct-96
13	GeneAmp PCR System 9700	Perkin Elmer	N805-0001 9700	805N7100239	01278447	Oct-97
14	Mettler Toledo Balance	Mettler	PG503-S	1119212534		Sep-00
15	Harris 20 c. ft., -85 deg. C. upright freezer with alarm and accessories	Harris	SLT-21V-85A34	W21K-498648-WK		Nov-00
16	Isotemp 27 c. ft., -30 deg. C. flammable materials freezer	Fisher	426R	010N0013		Nov-00
17	Zebra bar code/label printer (direct thermal thermal transfer)	Zebra Technologies	Z4M	3363754		May-03

2. DATA AND SOFTWARE SYSTEMS

	System	Item	Form
1	PT and real-time data tracking	Data	Spreadsheets, MS-Word files
2	Assay research	Data	Spreadsheets, MS-Word files
3	QCM data tracking	Data	Spreadsheets, MS-Word files
4	Data management system	Software	LDMS