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

RFP-NIH-NIAID-DAIDS-05-18
AIDS Research and Reference Reagent Program

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:** December 21, 2004	4. **Due Date:** March 7, 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.)

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

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

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

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

12. **Period of Performance:**
7 years begin on or about September 26, 2005

13. **Primary Point of Contact:** **Name : Liem T. Nguyen, CS** **Phone:** 301-451-3687 **Fax:** 301-480-4675 **E-Mail:** ln18x@nih.gov	14. **Secondary Point of Contact:** **Name: Barbara A. Shadrick, CO** **Phone:** 301-496-7288 **Fax:** 301-402-0972 **E-Mail:** bs92y@nih.gov	15. **Protest Officer:** 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)

DELIVERY ADDRESS INFORMATION

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

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

TABLE OF CONTENTS

BACKGROUND

AIDS Research and Reference Reagent Program
DAIDS 05-18

The purpose of this contract is to support the National Institutes of Health (NIH) AIDS Research and Reference Reagent Program (ARP) in achieving its goal of providing critical research reagents and resources to the scientific community. An important rate-limiting step in basic research is the identification and distribution of state-of-the-art reagents and technology. To address this need, the National Institute of Allergy and Infectious Diseases (NIAID) supports the ARP as a contract. Since its establishment in 1988, the ARP has evolved from a small bank of research materials to a unique and versatile worldwide resource of critical reagents not otherwise readily available to the HIV/AIDS research community. In 2002, the ARP contract was amended to provide reagents for biodefense research and other infectious diseases including transmissible spongiform encephalopathies (TSE). In addition to research reagents for HIV/AIDS, the ARP has provided reagents for hepatitis C virus, anthrax and Severe Acute Respiratory Syndrome (SARS) coronavirus research. The ARP acquires state-of-the-art reagents; produces these reagents, standardized panels, and protocols; and then provides these reagents at minimal cost to qualified investigators throughout the world. Additionally, the ARP collects information about AIDS-related reagents and standards and disseminates this information through print, electronic media, and enhances technology transfer by developing standard reagents and kits, and sponsoring workshops on their use. The ARP facilitates commercial development of reagents through proactive communications with biotechnology and pharmaceutical companies. In 2002, the ARP promoted commercial development of MHC class I/peptide tetramers by developing market for these reagents. Availability of quality controlled, custom made tetramers through the ARP resulted in their increased use and demand, now met by the commercial sector. The ARP participates as an AIDS Collaborating Center of the joint United Nations Program in HIV/AIDS (UNAIDS), and the United Kingdom's National Institute for Biological Standards and Control (NIBSC) Centralized Facility for AIDS Reagents.

Contributors and users include scientists from the NIH, academic institutions, non-profit institutions, and industry. The success of the ARP is evident in the expanding network of users. Over 2,000 scientists from 66 countries in North and South America, Europe, Asia, Africa, and Australia have registered and obtained reagents from the ARP. During the past year, there have been over 2,100 shipments of 20,000 reagents. More than 2,300 scientific publications have referenced the use of reagents obtained from the ARP. Approximately 10% of activities of the ARP involve other government-sponsored activities (e.g., participants may be collaborators in NIAID cooperative agreements, AIDS Clinical Trial Groups (ACTG), HIV Vaccine Trials Network (HVTN), HIV Prevention Trials Network (HPTN) investigators, and NIAID Contractors). Thus, the ARP is a major provider of reagents to HIV/AIDS investigators and also provides technical assistance in handling and shipping infectious materials throughout the world.

The current seven-year contract with McKesson Bioservices Corporation, Germantown, MD, (N01-AI-85332) expires on September 29, 2005.

Potential Offerors can review the website for detailed information on the ARP, its operations, and its contents at: http://www.aidsreagent.org/ .

STATEMENT OF WORK

AIDS Research and Reference Reagent Program

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 work described below.

The Contractor is required to perform the following tasks in support of the "NIH AIDS Research and Reference Reagent Program" – referred to as ("ARP"):

1. Operate the Current ARP and Identify Possible Improvements
2. Identify, Acquire, Produce and Expand Reagents
3. Quality Control of Reagents
4. Provide and Maintain Facilities and Resources for Storage and Processing of Reagents
5. Approvals, Assurances, Management and Distribution of Reagents and Materials
6. Ship and Receive Reagents
7. Disseminate Public Information Concerning Reagent Availability
8. Provide ARP Resource Support
9. Organize ARP-Sponsored Workshops
10. Maintain and Upgrade the ARP Inventory and Distribution Database
11. Coordination with Project Officer
12. Transition of the ARP

1. OPERATE THE CURRENT ARP AND IDENTIFY POSSIBLE IMPROVEMENTS

The Contractor will safely and effectively coordinate the transfer of the contents of the ARP and begin operation during the first 90 calendar days of the contract. The Contractor must use the current systems and applications to ensure continuity during the first twelve months of the contract. During this period, the Contractor will identify possible changes and improvements for potential adoption.

The Contractor will comply with local, State and Federal Regulations and requirements including Safety Controls and Standards; Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 26; PHS Policy on Humane Care and Use of Laboratory Animals, latest version, of the Guide for the Care and Use of Laboratory Animals **(see ATTACHMENT A.1)**; and Data Management, Communications and Systems Development Requirements **(see ATTACHMENT A.2).**

Currently, ARP information is accessible to users on the Internet at: http://www.aidsreagent.org. The site was developed using ColdFusion and JavaScript and occupies 1 GB of space. It provides a secure site for registrants to order reagents, print data sheets, start a reagent donation process, and access information about the ARP. The Contractor must continue providing ARP information on the Internet and keep the ARP current with advancing technology for the Internet in compliance with Information Technology (IT) systems security and/or privacy specifications; the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, A "Security of Federal Automated Information Systems", and the DHHS Automated Information Systems Security Program (AISSP) Handbook and its latest revisions, found at http://irm.cit.nih.gov/policy/aissp.html.

2. IDENTIFY, ACQUIRE, PRODUCE AND EXPAND REAGENTS

a. Identify novel reagents that are not readily available, prioritize their acquisition based upon the needs of the HIV/AIDS research community, availability, quantity and cost and acquire these reagents after receiving approval from the Project Officer. The acquisition effort includes solicitations or donations

from domestic and international sources, purchase orders/subcontracts for producing reagents, and expansion of reagents, and quality control. The Contractor is prohibited from using these reagents for its own use, including commercial use.

b. Acquire other reagents determined by the Project Officer to be necessary for the needs of the emerging infectious diseases research community including NIAID Category A-C Priority Pathogens and emerging infectious disease agents (http://www.niaid.nih.gov/biodefense/bandc_priority.htm. **The Contractor will not be directly engaged in any activities involving Category A Pathogens that require handling under Biosafety Level (BSL-4) safety and containment conditions as described at http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf.**

c. Monitor the reagent inventory to ensure that sufficient quantities of reagents are available and re-purchase or produce sufficient quantities of depleted reagents to replenish the inventory based on need after receiving approval from the Project Officer.

d. Acquire reagents through a competitive process in accordance with FAR Part 13 Small Purchase Procedures and the prior consent requirements of FAR Part 44.

e. Keep proper documentation on file, supporting:

1) the cost justification for all reagent acquisitions; and
2) the criteria for evaluation of reagent source(s).

f. Produce reagents on approval of the Project Officer. Production of reagents includes expansion of renewable reagents, e.g., cell lines, viruses, microorganisms and recombinant DNA.

g. Produce and/or acquire reagents that include the following biological materials:

- HIV and related viruses
- infectious agents and pathogens
- uninfected and/or infected cell lines
- genetically manipulated prokaryotic/eukaryotic cell lines
- DNA libraries
- DNA clones
- body fluids, cells and tissues
- proteins and peptides
- monoclonal and polyclonal antibodies

Reagents also include:

- antiviral and anti-infective drugs and therapeutics
- chemicals, including small molecule libraries
- agents that monitor and modulate the immune system
- vaccines, vaccine constructs and vaccine adjuvants
- microbicides
- diagnostic tools and kits for detection and measurement

h. Produce, maintain and store materials in compliance with Good Manufacturing Practice (GMP) conditions.

i. Acquire and distribute specialized animal models (e.g. transgenic mice) to be used as a live source of reagents for investigators. Housing of animals may be subcontracted subject to compliance with the PHS Policy on Humane Care and Use of Laboratory Animals (http://grants1.nih.gov/grants/olaw/references/phspol.htm). Animal welfare assurance and Institutional Animal Care and Use Committee (IACUC) certifications is required.

3. **QUALITY CONTROL OF REAGENTS**

a. Perform quality control for assays for validation and evaluation of reagents, to include:

- clonality
- purity
- sterility
- stability
- chemical composition, nucleic acid sequence and amino acid analysis
- solubility
- neutralization and infectivity assays
- analysis by mass spectrometry, chromatography, electrophoresis, and/or nuclear magnetic resonance spectroscopy
- restriction enzyme analysis
- polymerase chain reactions
- immunoblotting
- *In situ* hybridizations
- tritiated thymidine incorporation, and
- biological activity.

b. Perform quality control assays for biological and chemical reagents. For biological specimens, the number and types of assays to be performed will require the prior approval of the Project Officer.

1) Biological reagents (for example):

- bacteria
- viruses
- parasitic organisms
- fungi
- body fluids
- cells
- tissues
- cell lines
- lysates
- antibodies
- nucleic acids
- protein and peptide preparations
- natural products.

2) Chemical reagents (for example):

- antimicrobials
- microbicides
- antivirals
- chemicals and other compounds or natural products which may be used for developing therapies against HIV/AIDS and related pathogens, and other infectious disease organisms.

c. Maintain and perform quality control of Good Manufacturing Practice (GMP)-produced materials in compliance with U.S. Good Clinical Practice (GCP) Requirements, and International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.

4. **PROVIDE FACILITIES AND RESOURCES FOR STORAGE AND PROCESSING OF REAGENTS**

a. Provide safe and secure facilities, equipment and other resources to receive, handle, propagate, vial, weigh and store potentially hazardous organisms and reagents, and maintain their activity or viability under Biosafety Level 2/ 3 (BSL2/ 3) containment.

b. Operate the facilities under aseptic and/or sterile conditions.

c. Provide a room in the facility separate from infectious biologics for vaccines, drugs, therapeutics and other materials produced under GMP or that may be destined for pre-clinical use.

d. Provide suitable air-conditioned floor space sufficient for the installation, storage and maintenance of equipment and all items necessary for the ARP and distribution operation.

e. Provide, maintain and operate facilities for the storage of bulk and packaged reagents at 4 to 8 degrees C., at -20 degrees C., at -40 degrees C., -80 degrees C., and in liquid nitrogen conditions.

f. Supply uninterruptible power to accommodate refrigerators/freezers and other equipment. House the equipment in an air-conditioned facility with the capacity to maintain a room temperature of 19 degrees to 22 degrees centigrade when all equipment is operating.

g. Assure that all refrigerators and freezers are connected to a central alarm system monitored 24 hours per day. The Contractor must have available emergency stand-by refrigerators and freezers in case of mechanical failure of established storage space. The facility must have a back-up auxiliary electric generator capable of operating all storage equipment, security systems and necessary lighting for at least 48 hours in the event of utility company power failure. The back-up generator must be tested monthly under continuous full load conditions for at least one hour.

h. Provide, maintain and operate surveillance systems to assure that the stored materials remain accessible only to authorized personnel. The Contractor must utilize a state-of-the-art electronic security system with fail-safe locking hardware to insure controlled access to all of the designated repository areas of the facility.

i. Provide systems to assure safe electronically controlled access to all reagents and related materials.

j. Provide, maintain and operate procedures to track and catalog, at prime and subcontractor locations, the handling and manipulation of stored HIV/AIDS agents, and NIAID Category A-C Priority Pathogens and emerging infectious disease agents and materials related to these agents. All computer systems must utilize state-of-the-art software firewalls, security systems and other software to prevent unauthorized access, and treatment of sensitive data in compliance with DHHS Automated Information Systems Security Program (AISSP) Handbook http://irm.cit.nih.gov/policy/aissp.html

k. Provide protective garments, equipment, training and monitoring to assure safe handling of toxic, biohazardous and potentially hazardous materials, including radioactive materials. **The Contractor must comply with all applicable health and safety regulations and follow the standards listed under Attachment A.1 to the Work Statement.**

l. Provide facilities for weighing or dispensing solid and liquid reagents into aliquots and labeled vials. Because of the nature of some reagents, facilities must be available for the appropriate handling of infectious agents, and for hazardous materials, including radioactive materials.

m. Provide a separate, locked, electronically-controlled access-restricted storage space (i.e., a safe, approximately 15 cubic feet) maintained at the appropriate temperature for hallucinogens, narcotics and other reagents designated by the Drug Enforcement Administration as dangerous and/or controlled substance compounds. The Contractor must comply with registration of manufacturers, distributors, and dispensers of controlled substances as provided in the U.S. DEA Controller Substances Act [see http://www.usdoj.gov/dea/pubs/csa.html.] These materials will be subject to cataloging and tracking as described for Category A-C agents (see paragraph j., above).

n. Provide and maintain 24-hour security for employees and materials within the facility.

o. Provide an automated 24 hour/day temperature monitoring system composed of individual probes controlled by a master computer. Establish measures to ensure that necessary personnel are notified in the event of a refrigerator/freezer malfunction. The Contractor is responsible for immediate repair of all malfunctioning equipment.

p. Provide appropriate storage for radioactive material in compliance with local, state and federal regulations.

q. All personnel, prior to beginning work on this contract, must be bonded and meet all local, state, and Federal Regulations, including registrations for access and handling of Category A-C Agents (http://www.niaid.nih.gov/biodefense/bandc_priority.htm), in compliance with requirements of the USA Patriot Act, Sec. 817. –Expansion of Biological Weapons Statute http://uscis.gov/graphics/lawsregs/patriot.pdf) and access to Select Agents, Appendix A to Part 72, CFR 42, http://www.cdc.gov/od/sap/.

5. **APPROVALS, ASSURANCES, MANAGEMENT AND DISTRIBUTION OF REAGENTS AND MATERIALS**

a. Use and update a record-keeping system that complies with local, State and Federal regulations and requirements governing access, distribution within a facility, transport, and use of infectious and biohazardous agents, including Category A-C Agents (http://www.bt.cdc.gov/Agent/Agentlist.asp).

b. Use and update a record-keeping system to verify that all investigators and institutions requesting agents or reagents are in compliance with the requirements of the USA Patriot Act, Sec. 817.– Expansion of Biological Weapons Statute http://uscis.gov/graphics/lawsregs/patriot.pdf.

c. Coordinate with the Project Officer for the distribution of reagents to approved investigators and institutions in accordance with operating procedures in compliance with all local, State and Federal regulations. The Contractor shall consult with the Project Officer for all questionable investigators/institutions or procedures.

d. Develop form letters to be used for acceptance or refusal of reagent requests.

e. Distribute materials only to institutions that, in addition to other assurances, execute agreements through Registration and Reagent Request Forms, Material Transfer Agreement, and associated documents and updates **(see ATTACHMENT A.3)** that comply with the following:

1) Certification of compliance with safety standards
2) Not to use reagents in any unauthorized or unsafe way, including compliance with Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 26; and PHS Policy on Humane Care and Use of Laboratory Animals, implementing 1996 revisions or latest versions of the Guide for the Care and Use of Laboratory Animals.
3) If commercial use is planned or commercial discoveries result through the use of a reagent, such use will occur only in accordance with the contributor-assigned Release Category for the reagent (**see ATTACHMENT A.3**).
4) The Contractor will secure, update and modify these agreements **(see ATTACHMENT A.3).**

6. **SHIP AND RECEIVE REAGENTS**

a. Obtain the appropriate licenses and permits required by local, State and Federal authorities for the safe import, handling, storage and distribution of reagents and drugs. Obtain appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biohazardous, infectious, and/or radioactive reagents and drugs.

b. Ship and receive reagents. The recipients are responsible for payment of all shipping costs.

c. Ship available reagents within seven working days from the date requests are received.

d. Ensure that all shipments comply with local, State and Federal regulations and requirements for distribution of reagents.

e. Unless prohibited by federal and/or state law, recipient investigators and their institutions assume all liability for claims for damages against it by third parties which may arise from the use, storage, or disposal of the reagent except that, to the extent permitted by federal and/or state law, the Providers will be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Providers. The legal process for filing and adjudicating claims against the Recipient or Providers will be subject to all applicable federal and/or state laws.

f. Provide outgoing reagent packages with data sheets containing technical information, references and citations of relevant information for safe handling and use of the reagents, and applicable safety standards. Delineate specific safety standards for handling and use of specific reagents in compliance with local, State and Federal regulations.

f. Provide safe packaging, shipping and distribution of reagents and drugs to eligible research investigators in the U.S. and abroad so that shipments are coordinated for timely receipt. A secure package tracking system must be utilized to ensure that all materials are delivered to the intended recipient.

g. Provide available personnel on a 24-hour, seven-day-a-week basis to pick up and store incoming shipments of reagents from any specified airport or other contract site in a timely manner to assure reagents are maintained at the required temperature until placed in the ARP. Because incoming shipments usually represent a substantial financial investment, it is essential that the Contractor coordinate shipments so that personnel are available to receive them whenever delivered and transport them to the ARP for storage at the required temperature. Upon receipt, all shipments must be maintained for stability and viability at the required temperature, for transit from the airport or other site to the ARP. The Contractor will revise airport shipping/receiving procedures and requirements as necessary to remain compliant with the U.S. Department of Transportation regulations.

h. Coordinate all shipments so that viability, biological activity and/or purity of the reagents will not be adversely affected. Send notification by internet/facsimile to all foreign and domestic investigators to coordinate shipment and receipt.

i. Use shipping containers for reagents that comply with current domestic and international transport regulations and pertinent (IATA) International Air Transport Association/International Civil Aviation Organization Dangerous Goods Regulations. http://www.iata.org/dangerousgoods/about.htm.

j. Use shipping containers with sufficient margins of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.

7. **DISSEMINATE PUBLIC INFORMATION CONCERNING REAGENT AVAILABILITY**

a. Promote awareness of the ARP's services throughout the scientific community using electronic and print media, lease booths or poster presentations at scientific meetings, symposia and workshops, and as otherwise recommended by the Project Officer.

b. Develop, maintain and periodically update the ARP internet site including the ARP catalog, Web-based registration, reagent ordering/donating system, LISTSERV news groups, electronic bulletin board, and links to other reagent resources. The Website must conform to Section 508 (ADA), Privacy Act, and Government standards regarding usability, "cookies"/information collection.

c. Prepare an HTML and camera-ready hardcopy of the catalog of available reagents and arrange for printing. The hardcopy will be reviewed and approved by the Project Officer prior to printing. The catalog will be prepared annually with a publication date of January of each year (the first catalog will be published in January 2006). It is anticipated that approximately 3,000 copies will be required for distribution, annually. The Contractor will distribute the catalogs to the scientific community on the ARP mailing list (approximately 2500 copies), and to others upon request.

d. Publish descriptions of portions of the ARP collection in relevant scientific journals as recommended by the Project Officer.

e. Interface, integrate or adapt ARP information system(s) to interact with current and future components of the DAIDS Enterprise System (DAIDS-ES) in compliance with technology for the Internet and in compliance with the Information Technology (IT) systems security and/or privacy specifications; the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, A "Security of Federal Automated Information Systems", and the DHHS Automated Information Systems Security Program (AISSP) Handbook and its latest revisions.

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

g. 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 the NIAID Office of Technology Information Systems (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 resulting in a decision on direction and the software, OS's, languages and tools to be used, must be completed.

h. Perform data entry or interact with other NIAID contracts for the exchange of data, movement of samples and investigational products. Download or transfer data to other supported databases upon request.

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

8. **PROVIDE ARP RESOURCE SUPPORT**

a. Support collaborative efforts of the NIAID and the Division of AIDS with investigators by providing reagents and information, including reference standards and reagent panels, such as PCR standards, DNA libraries, viral and microbial isolates, novel immunological reagents, antibodies, microbicides and drugs.

b. Get feedback from users of the ARP on an annual basis to assess quality, usefulness, timely delivery of reagents, and other services provided by the Contract.

9. **ORGANIZE ARP-SPONSORED WORKSHOPS**

a. Under the guidance of the Project Officer, the Contractor will organize and sponsor workshops to:

1) distribute protocols and technology;
2) develop reagents and/or protocols;
3) prioritize reagent acquisitions;
4) promote technology transfer; and
5) promote compliance with regulations for packaging and shipping of infectious substances.

b. Provide travel and per diem expenses for approximately 10 out-of-town participants in compliance with NIH policy (see NIH Policy Manual: http://www1.od.nih.gov/oma/manualchapters/management/1160-1/).

10. **MAINTAIN AND UPGRADE THE ARP INVENTORY AND DISTRIBUTION DATABASE**

Maintain and upgrade the existing PC-compatible AIDS Reagent Management System (**ARMS, see ATTACHMENT A.4., for details**) to track and assist in the coordination and management of the ARP, to include the following activities:

a. Keep records for each reagent, to include the following:

- source/donor of the reagent
- date of receipt
- full description of the reagent
- lot number
- category of reagent (e.g. not of human origin, human-derived, biohazardous, radioactive, donor-assigned category for commercial use)
- quality control information
- storage conditions
- solubility of the reagent
- storage location
- restrictions, if any, on disposition and uses
- how dispensed and to whom
- shipping date and recipient's address by whom it was shipped
- documentation of receipt

b. Read and generate bar-coded labels for 1.8 ml reagent vials in different formats including numeric, alpha numeric, and colored bar codes. **Material (software and hardware) for maintaining records in paragraph 10.a., above must be provided by the Contractor.**

c. Ensure protection against the loss of data by duplicating database files and programs for storage outside of the ARP. The system in its entirety must be completely documented and capable of being transferred to the Government without interruption at any time.

d. Provide for security and safety of reagent data and all information related to evaluation and use of the reagents. All information regarding: 1) the proposed use of reagents by recipients, 2) identity of regents not published in the Catalog, and 3) identity of identifiers linked to individuals from whom any human-derived reagent was obtained, is considered proprietary and shall be treated as such. The Contractor is prohibited from releasing, publishing, or disclosing sensitive information to unauthorized personnel, and is required to protect sensitive information in accordance with the provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information: 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records); 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and Public Law 96-511 (Paperwork Reduction Act). The Project Officer will be responsible for determining the level of information availability and to whom information can be made available, regarding any and all reagents.

11. **COORDINATION WITH PROJECT OFFICER**

The Contractor's key personnel, including the Principal Investigator, will meet with the Project Officer at periodic intervals to review the project and discuss the work to be performed.

12. **TRANSITION OF THE ARP**

a. The Contractor is required to perform an orderly and safe transition within a 90 calendar day period to include the movement of all stored reagent samples, all Government-furnished property and the following items, to a successor contractor or the Government, on or before the completion date of this contract.

1) preserved reagent samples,
2) data files and materials comprising the AIDS Reagent Management System,
3) computerized listings of accurate and updated information on reagent inventory, data files, databases, original data and any necessary information related thereto,
4) labeled and inventoried paper files, and
5) Government furnished property.

b. The Contractor will develop a Transition Plan to ensure a timely and orderly transfer. A DRAFT Transition Plan is to be submitted 24 months after the effective date of the contract. A FINAL Transition Plan is to be submitted 12 months prior to the completion date of the contract. These Plans are to be submitted to the Project Officer and Contracting Officer for review and approval. At a minimum, the transition plans are to include the following:

1) A schedule for delivery of data, datasets, databases, and/or systems used and developed under this contract to the Project Officer or designated entity.

2) A cleaned and edited public use data set, on media to be determined at the time of delivery, as specified by the Project Officer, and copies of all data management tools, including, but not limited to, data documentation and data dictionaries, data entry software and editing programs to allow reading and analysis of the data.

3) Appropriate computer programs capable of reading and manipulating all data and creating databases.

4) An audit trail of all raw data corrections, hard copies of the original data collected and all logs and other records related to data collection, entry, editing, analysis and transfer.

5) All electronic files in a format specified by the Project Officer.

6) Transfer all hard copy files in an organized manner, as specified by the Project Officer, to a location specified by the Project Officer.

7) Maintaining a fully operational capacity through the completion date of the contract.

8) List of facilities and equipment support provided and any scheduled support to be provided during the transition period.

9) List of subcontracts with a transition plan to either continue through transition to another Contractor or close out if the subcontract is at its completion date. If the contract is transitioned to a new Contractor, all subcontracts must be closed out to coincide with the completion date of the prime contract. The successor contractor will negotiate new subcontract agreements.

10) At a minimum, both the DRAFT and FINAL transition plans will include an estimate of cost, time frame to complete transition, and the staff required to execute a successful and timely transition.

[END OF STATEMENT OF WORK]

SAFETY CONTROLS AND STANDARDS

a. In order to provide safety controls for (1) employees' and other persons' life and health protection, (2) the prevention of damage to property, and to avoid work interruptions in performance of the contract, the Contractor will comply with the following:

(1) "Biosafety in Microbiological and Biomedical Laboratories," U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH, Fourth Edition (and updates) http://www.cdc.gov/od/ohs/biosfty/biosfty.htm; http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf
(2) Update: "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood borne Pathogens in Health-Care Settings." Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.
(3) Appendix A to Part 72, CFR 42, Select Agents http://www.cdc.gov/od/sap/; http://www.cdc.gov/od/sap/docs/42cfr73a.pdf, and Part73.4 and 73.5, CFR 42 http//www.cdc.gov/od/sap/docs/42cfr73a.pdf.
(4) If animals or animal products will be used: http://www.aphis.usda.gov/vs/ncie/bta.html
(5) "Recommendations for the Safe Handling of Parentoral Antineoplastic Drugs," NIH Publication No. 92-2621: http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm
(6) NIH Chemical Hygiene Plan http://www.nih.gov/od/ors/ds/pubs/chp/index.html

(7) Occupational Safety and Health Administration (OSHA) Publications:

a) 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule, and;
b) 29 CFR Part 1910, Occupational Exposure to hazardous chemicals in Laboratories, Final Rule.

(8) NIH Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplement (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

Items (1)-(7) may be obtained from:

Division of Safety, Office of Research Services
Office of the Director, National Institutes of Health
Bethesda MD 20892-2260
301-496-1357

(9) "Procedures for the Domestic handling and Transport of Diagnostic Specimens and Etiologic Agents," National Committee for Clinical Laboratory Standards, July 17, 1985, Vol. 5. This may be obtained from:

National Committee for Clinical Laboratory Standards
771 East Lancaster Avenue
Villanova PA 19085

Additionally the Contractor must comply with the following regulations governing handling, transportation and import/export of etiologic agents from:

Title 42 Part 72.6, "The Select Agent Rule"
Effective date: April 15, 1997
http://www.cdc.gov/od/sap/42cfr72.htm
Effective Date December 13, 2002
http://www.cdc.gov/od/sap/docs/42cfr73.pdf

Effective date November 3, 2003
http://www.cdc.gov/od/sap/docs/42cfr73a.pdf
Appendix F, Laboratory Security and Emergency Response for Microbiological and Biomedical Laboratories
Appendix I, Guidelines for Work with Toxins of Biological Origin
http://www.cdc.gov/od/sap/addres.htm
Regulations governing the shipment of select agents and biohazards
Application for Registration to receive select agents
http://www.cdc.gov/od/sap/downloads2.htm ; http://www.cdc.gov/od/ohs/lrsat.htm
Regulation for the importation of etiologic agents
USPHS 42 CFR - Part 71.54 - Importation of etiologic agents, host and vectors of human disease.
USDA, 9 CFR Parts 92, 94, 95, 96, 122 & 120. - Importation or domestic transfer of etiologic agents of livestock, poultry, and other animal diseases
DOC, 15 CFR Parts 730-799 -Export of items on the Australia Group list. Bureau of Export Administration, DOC
DOT, 49 CFR Part 171 – Research and Special Programs Administration, DOT - General information, regulations, and definitions
Rules governing the illegal possession of a biologic agent
Antiterrorism and Effective Death Penalty Act of 1996
Sec. 511. Enhanced Penalties and Control of Biologic Agents
Public Law 104 - 132; April 24, 1996
USA Patriot Act: Sec. 817 – Expansion of Biological Weapons Statute
http://uscis.gov/graphics/lawsregs/patriot.pdf
S. 1706 - Bioweapons Control and Tracking Act of 2001 (11/15/2001)
http://www.securitymanagement.com/library/S1706_bioterror0202.pdf
H.R. 3448 - Public Health Security and Bioterrorism Response Act of 2002
http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_bills&docid=f:h3448enr.txt.pdf
Limitation on Issuance of Hazmat Licenses (DOT)
License to operate a motor vehicle transporting in commerce a hazardous material - Sec. 1012 - Requires a background records check: Possession by Restricted Person - sec. 175b - No restricted person shall ship, possess, or receive a Select Agent.

Further, the Contractor shall take, or cause to be taken, such additional safety measures as reasonably necessary; provided, that if compliance with such additional safety measures results in a material increase in the cost or performance effort of the contract, an equitable adjustment will be negotiated with the Contracting Officer in accordance with the clause in this contract entitled “Changes."

ATTACHMENT A.2

Data Management, Communications and Systems Development Requirements:

The contractor will, as appropriate:

a. Establish and administer state of the art, efficient, reliable, secure and responsive systems for the collection, management, quality assurance and reporting of study data, as well as a system for electronic communication linkages among investigators, the NIAID, the protocol teams, and the Contract Executive Committee.

b. Develop computer programs and related procedures for the collection, processing, editing, and analysis of all clinical and laboratory study data, including storage, tracking, and retrieval of study data at the central data management facility.

c. For studies involving human beings, demonstrate compliance with all applicable domestic and international regulations on the use of human subjects in research, including HIPAA and Privacy Act rules and regulations.

d. Evaluate and improve the accuracy, timeliness, and completeness of data submitted by the investigators and reagent donors at each stage through creation of final datasets, including verification of the clinical and laboratory data used to determine that study participants have reached protocol-defined endpoints.

e. Provide a state of the art computer 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 a study. The system shall provide sufficient flexibility and accessibility to answer any inquiries in a timely manner, typically no more than one business day.

f. The contractor will (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, but is not limited to: IT architecture (network, security, server, application, and database), schemas, run books, processes, procedures, disaster recovery, failover, troubleshooting, application/system monitoring, change control/management.

g. If this project involves Information Technology, the contractor must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The contractor will also need to include similar information for any subcontract proposed.

   The difference between the "Information Technology System Security Program" that is required as standard RFP language in section L and the specific “Information Technology Security Plan Information Security (InfoSec) Plan” required to be submitted by the Contractor after award, relates to the contractor’s organization’s System Security Program as opposed to a specific plan to address the requirements of this contract. This information must be submitted after award.

h. Information Security (InfoSec) consists of:

   1. Confidentiality: the prevention of unauthorized disclosure/use of information.
   2. Integrity: the prevention of unauthorized modifications to information.
   3. Availability: ensuring the reliable and timely access to data or computing resources.

i. 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, FWD IRN, 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 to:

1. Describe the level of physical and electronic security required based on the needs described in the Statement of Work, including Privacy Act, CDC, USDA rules and Patriot Act requirements, as well as patient information and other areas determining the level of security the offeror proposes to implement.
2. Provide security against unauthorized access and use of the computer system and data. All computer systems must utilize state-of-the-art software firewalls, computer security systems and other computer software to prevent unauthorized access to the computer system and to prevent "hacking" by those outside the secure system.
3. Provide security measures that ensure the facility, equipment, software, systems and data against natural disaster, fire and personal intrusion.
4. Ensure patient confidentiality for all subject records (both hard copy and electronic).
5. Ensure compliance with all applicable areas of the Homeland Security Act and the DHHS AISSP Handbook
6. Provide security against anticipated risks, including loss of confidentiality of subject records and viral or catastrophic loss of study data or important software.
7. Provide security against unauthorized use of data associated with Bioterrorism agents.

j. Maintain and update a computerized inventory and database system relating to all computer hardware, software, data and other items. Ensuring safe and orderly transition of all materials and data to a successor at the end of the Contract.

REGISTRATION FORM

Instructions

Please read these instructions carefully:

Eligibility

To register with the NIH AIDS Reagent Program, you must be a Principal Investigator, Laboratory Director, or equivalent (public or academic institution), or a Director of Research or equivalent (private or for-profit institution).

Procedure

Registrants must submit the documents outlined below. Registration documents must contain original, ink signatures.

The NIH AIDS Reagent Program cannot accept registration forms by FAX.

1. Registration Form

The form must be signed by the registrant and countersigned by an official capable of legally binding the institution (e.g. president, vice-president, dean, or provost, but NOT a department chairman).

2. Biographical Sketch

Attach a Biographical Sketch that includes a listing of five recent, representative publications, or a brief curriculum vitae. A Biographical Sketch from a recent NIH grant proposal may be submitted instead.

Shipping Costs

There is no charge for reagents; however, requesters are required to pay all shipping costs by establishing an account with an overnight shipping company and providing their account number to the NIH AIDS Reagent Program. The NIH AIDS Reagent Program will not bill requesters for shipping charges; you MUST provide an account number so that your shipping company can bill you. Your carrier must be able to ship packages containing dry ice and biohazardous materials, if applicable. Reagents will not be shipped collect.

Mail your completed registration forms to:

NIH AIDS Research and Reference Reagent Program
McKesson BioServices Corporation
20301 Century Boulevard
Building 6, Suite 200
Germantown, Maryland 20874
USA

REGISTRATION FORM

Effective January 1, 2001 - September 29, 2005

Registrant Information	
Name :	
Title:	Email:
Institution:	
Institution Type (check one): ☐ Non-profit Organization ☐ Commercial Organization	
Telephone :	FAX:

Shipping Information
Full Shipping Address: (Please write the address exactly as it should appear on a mailing label. Reagents will not be shipped to a post office box.):
Shipping Company
Shipping Company Account Number

Research Support (Please specify types and Grant/Award Numbers)	
Funding Outside of United States	Other Federal Funding
Industry	Other
NIH Extramural Research	Private Foundation
NIH Intramural Research	State Funding

Liability

Requester's Institution acting through its investigator ("Recipient") agrees that any reagent delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The United States Government, McKesson BioServices Corporation, and their Suppliers and contributors of reagents ("Providers") MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE REAGENT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by federal and/or state law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage, or disposal of the reagent except that, to the extent permitted by federal and/or state law, the Providers shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Providers. The legal process for filing and adjudicating such claims against the Recipient or Providers will be subject to all applicable state and/or federal laws.

Certification of Compliance with Safety Standards

Recipient is aware that all reagents distributed by the NIH AIDS Reagent Program may be potentially biohazardous even when they are not specifically designated by a biohazard symbol (☣). Recipient understands that the requested reagent(s) may pose health risks to persons handling or in the vicinity of the reagents, the environment, and the community. Recipient is cognizant of and will employ the appropriate biosafety standards including special practices, equipment, and facilities. Recipient shall comply with all applicable Institution and Government health and safety regulations and the guidelines detailed in: Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, May, 1999, GPO Stock No. 017-040-00547-4, or the most recent revision of these guidelines. Recipient shall directly supervise all users of the reagent(s) and shall assume responsibility for assuring that those users are cognizant of and comply with safety standards and good laboratory practices.

Human Use

Recipient agrees to comply with Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46. None of the reagents provided by the NIH AIDS Reagent Program nor any Derivatives (defined as essentially unmodified progeny or materials created by the Recipient that incorporate a previously known unmodified functional subunit or product expressed by the original material) will be used in humans or for any clinical diagnosis without receiving prior written approval of the reagent contributors and the Director, Division of AIDS, NIAID, NIH. The intent of these conditions is to protect both the rights and the welfare of human subjects, and to protect reagent contributors and the NIH AIDS Reagent Program.

Animal Use

Recipient agrees that reagents provided by the NIH AIDS Reagent Program and any Derivatives will be used in animals only as described in: Public Health Service Policy on Humane Care and Use of Laboratory Animals, October, 2000, or the latest version thereof (copies may be obtained from the NIH Office of Laboratory Animal Welfare, TEL: 301-594-2506, email: olaw@od.nih.gov

Certification of Use

With the exception of reagents used for commercial purposes under the conditions set forth under Commercial Discoveries below, Recipient certifies that all reagents provided by the NIH AIDS Reagent Program, or Derivatives, will be used for research purposes only, in Recipient's laboratory only, at Recipient's Institution only, and only for the experiments proposed on the Reagent Request Form. Also, the reagents or Derivatives will not be allowed to come into the possession of any other persons except those engaged in research under Recipient's direct supervision who accept these restrictions.

Assumption of Shipping Costs

Recipient agrees to assume the costs of shipping reagents by providing an overnight carrier shipping account number, or by making arrangements for prepaid shipments. Recipient shall confirm that the carrier is willing to ship biohazardous materials and can pick up shipments from the NIH AIDS Reagent Program. No shipments will be made until Recipient's proposed shipping arrangements are accepted by the NIH AIDS Reagent Program.

Commercial Discoveries

Recipient agrees that before a reagent is used in a product offered for sale, in a commercial manufacturing process, including quality control procedures, or as part of a fee-for-service activity, such use will occur only according to the contributor-assigned Release Category described below. Note: Reagent contributors may change their Release Category assignment. Recipient is expected to abide by the reagent assignment that is in place at the time the reagent is received.

If Recipient wishes to use the reagent under the terms of a revised release category assignment, then Recipient must submit a new Reagent Request Form.

Release Category	Description
A	Reagent may be used for commercial purposes without an agreement with the reagent contributor.
B	Recipient agrees to negotiate in good faith to share with the reagent contributor's Institution the income arising from commercializing the reagent.
C	Recipient must sign an agreement with the reagent contributor's Institution for commercial use prior to receiving the reagent.
D	Recipient must select Release Category B or C prior to receiving the reagent.
E	Recipient must not use or incorporate the reagent for commercial purposes.

Acknowledgment of Source

Recipient agrees to acknowledge in all publications and presentations of studies utilizing reagents supplied by the NIH AIDS Reagent Program both the contributors of the reagents and the NIH AIDS Reagent Program. The suggested form for acknowledgments is: "The following reagent was obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH: (reagent name) from (reagent contributor name)." Recipient agrees to provide copies of all publications and abstracts of presentations to the NIH AIDS Reagent Program.

Reporting Agreement

Recipient agrees to provide the NIH AIDS Reagent Program with a description of the planned use of the requested reagents with each request. Recipient agrees to provide the NIH AIDS Reagent Program with an annual summary of results and a reagent status report. Recipient's obligation to provide annual reports will end when the reagent(s) or any Derivatives are no longer in Recipient's possession.

*Officer of Institution or Company (Signature)	Requester (Signature)
Printed Name:	Printed Name
Title:	Title
Institution:	Institution
Date	Date:

*The officer cosigning above must be capable of legally binding the Institution.

REGISTRATION FORM (BIOGRAPHICAL SKETCH)

This form, or a Biographical Sketch from a recent NIH grant proposal, may be submitted to the NIH AIDS Reagent Program in lieu of a curriculum vitae.

Name:
Position/Title:

Education

Begin with Baccalaureate or other initial professional education and include postdoctoral training:

INSTITUTION AND LOCATION	DEGREE	YEAR CONFERRED	FIELD OF STUDY

Research and Professional Experience

Concluding with your present position, please list, in chronological order, your three most recent professional positions.

EMPLOYER	TITLE	DATE OF EMPLOYMENT

Publications

Please list five recent representative publications:

1.

2.

3.

4.

5.

REAGENT REQUEST FORM

Instructions

The NIH AIDS Reagent Program can only provide reagents to individuals who are registered users.

This year we have in place an electronic Paperless Ordering System (POS) that may be used instead of submitting orders by FAX or mail. Once the order is received electronically, the user needs to confirm it by responding to the alert sent to his/her email address. Only the registered user's email address can be used for the POS. See the FAQ at www.aidsreagent.org for help with the POS.

An order submitted with a new registration application will be accepted, but it cannot be processed until the registration has been approved.

To order reagents:

1. A registered user must have a valid account number with an overnight shipping company. Also, the user should check with his/her institutions to determine whether a billing number or purchase order number is needed; if so, that number should be added to the order form in the space indicated.

2. The options for placing an order are:

- Go to **www.aidsreagent.org** and follow the instructions for ordering, or

- Complete a hard copy Reagent Request Form and submit it by FAX or mail. Include the user's registration account number on the form in the space indicated. Submit the order to:

NIH AIDS Research and Reference Reagent Program
20301 Century Boulevard
Building 6, Suite 200
Germantown, Maryland 20874
TEL: 240.686.4740
FAX: 301.515.4015

REAGENT REQUEST FORM

Effective August 1, 2000 - September 29, 2005

Name of Registered Requester:	
NIH AIDS Reagent Program Account Number:	
Telephone:	FAX Number:
Shipping Co.:	Shipping Co. Account Number:
Does your institution require an internal billing number for shipping charges? YES NO	
Billing/Purchase Order No. (if you indicated Yes above):	
Animal Welfare Assurance No. (if a reagent is to be used in animals):	
Radioactive Materials License No. (if ordering radiochemicals):	

Cat. No.	Reagent	Intended for Commercial Use?*	To be Used in Animals	IACUC Protocol Approval No. and Date (for animal use only)	Send Data Sheets?
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO
		YES/NO	YES/NO		YES/NO

*Complete the Acknowledgment of Commercial Rights (page 10) when ordering Release Category B or D reagents for commercial use.

PERSONNEL ENGAGED ON PROJECT		
NAME	POSITION TITLE	ROLE IN PROJECT

REAGENT REQUEST FORM (ABSTRACT OF PROPOSED REAGENT USE)

I request the reagents listed on the Reagent Request Form from the NIH AIDS Research and Reference Reagent Program. I agree to adhere to all conditions and agreements in my Registration Form. I agree that reagents provided by the NIH AIDS Reagent Program and any Derivatives (as defined in the Registration Form) of said reagents will be used in animals only as described in: Public Health Service Policy on Humane Care and Use of Laboratory Animals, October, 2000, or the latest version thereof (copies may be obtained from the NIH Office of Laboratory Animal Welfare, TEL: 301-594-2506).

I agree to comply with Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46. I agree that none of the reagents provided by the NIH AIDS Reagent Program, nor any Derivatives of said reagents, will be used in humans or for any clinical diagnosis without receiving prior written approval of the reagent contributor and the Director, Division of AIDS, NIAID, NIH.

I agree to adhere to the contributor-assigned Release Category for commercialization of the reagents I receive from the NIH AIDS Reagent Program.

I agree to acknowledge the NIH AIDS Research and Reference Reagent Program and the use of the reagents in any resulting publication or presentation.

I agree to be responsible for an annual reporting agreement until I no longer have the reagent(s) or any Derivatives of the reagent(s) in my possession.

I understand that radioactive materials will be shipped to my Radiation Safety Officer, and not to my laboratory.

ONLY THE REGISTERED REQUESTER MAY SIGN THIS FORM	
Requester (Signature):	Date:

ADDITIONAL FORMS

Instructions

Additional documentation is required when requesting some of the regents described in this Catalog. Read the reagent description carefully to determine which forms may be required.

Do not submit any of these forms unless you are requesting reagents that require them.

1. Acknowledgment of Commercial Rights

Submit this form when requesting a reagent for commercial use that has been assigned to Release Category B or D (see page 4 for a description of the Release Categories). You must also submit the Reagent Request Form with your order.

2. WHO - UNAIDS Materials Transfer Agreement

FOR SCIENTISTS AT NON-PROFIT INSTITUTIONS ONLY. NOT REQUIRED FOR SCIENTISTS IN U.S. GOVERNMENT INSTITUTIONS.

Submit this two-page form when requesting WHO - UNAIDS-provided materials. A Reagent Request Form is NOT required for these reagents.

Scientists at commercial organizations should NOT complete this form; instead fill out the WHO - UNAIDS MTA for use by for-profit institutions.

3. WHO - UNAIDS Materials Transfer Agreement

FOR SCIENTISTS AT FOR-PROFIT INSTITUTIONS ONLY

Submit this three-page form when requesting WHO - UNAIDS-provided materials. A Reagent Request Form is NOT required for these reagents.

4. Statement of Investigator for IL-2

Submit this form when requesting IL-2 (Catalog #136). You must also submit the Reagent Request Form with your order.

5. AnorMed

Submit this form when requesting bicyclam JM-2987 (hydrobromide salt of AMD-3100) (Catalog #8128) in addition to the Reagent Request Form.

6. APATH

Submit this form when requesting any of the Apath LLC reagents (Catalog #7668 thru #7676) in addition to the Reagent Request Form.

7. T-20 Addendum

Submit this form when requesting any of the T-20 reagents (Catalog #9409 and #9845) in addition to the Reagent Request Form.

ACKNOWLEDGEMENT OF COMMERCIAL RIGHTS

DO NOT SUBMIT THIS FORM IF THE REAGENT IS TO BE USED FOR RESEARCH PURPOSES ONLY.

Reagents that have been assigned to Release Category C cannot be provided to requesters for commercial use without written permission from the reagent contributor. Contact the reagent contributor for information about licensing and other requirements.

Release Category B and D Reagents

Reagents that have been assigned to Release Category B or D can be used for commercial purposes if this form is completed and submitted with the Reagent Request Form.

I REQUEST THE FOLLOWING REAGENT:		
CATALOG NUMBER	REAGENT NAME	RELEASE CATEGORY

FOR RELEASE CATEGORY B REAGENTS ONLY

Sign the following statement:

I agree to negotiate in good faith to share with the contributor's institution any income arising from commercializing the reagent.

Requester (Signature):	Date:

FOR RELEASE CATEGORY D REAGENTS ONLY

Check ONE of the following boxes:

☐ I accept the reagent according to Release Category B.
I agree to negotiate in good faith to share with the contributor's institution any income arising from commercializing the reagent.

OR

☐ I accept the reagent according to Release Category C.
An agreement signed by my institution and the contributor's institution for commercial use of the reagent is attached.

Requester (Signature):	Date:

FOR SCIENTISTS AT NON-PROFIT INSTITUTIONS ONLY.
NOT REQUIRED FOR SCIENTISTS IN U.S. GOVERNMENT INSTITUTIONS.

WHO - UNAIDS
HIV Vaccine Initiative*

* The WHO-UNAIDS Vaccine Initiative is a joint activity of the World Health Organization (WHO) and the United Nations Programme on HIV/AIDS (UNAIDS).

Reagent(s) Requested (please list all reagents):

Justification for Request (continue on separate sheet if necessary):

1. You will not permit the Materials or any part of them to come into the possession or control of any other persons except those engaged in research under your supervision who have accepted the same obligations as yourself in respect of the Materials.

2. You will use the Reagents for research purposes only and will not use them or permit them to be used in any way for the production or sale of any products for commercial purposes, without prior authorization in writing from the WHO - UNAIDS.

3. The Reagents (or materials derived from them) WILL NOT be used in humans without the prior authorization in writing from the WHO - UNAIDS.

4. Any publication or presentation of your work with the Materials will duly acknowledge the WHO - UNAIDS, the original contributor of the Reagents, and the NIH AIDS Research and Reference Reagent Program.

5. On conclusion of the research programme using the Materials, you will continue to abide by the obligations and restrictions set out in this letter.

6. Any infectious or potentially infectious Materials will be handled in appropriate containment facilities by fully trained and competent staff (see WHO Biosafety Guidelines: WHO/AIDS Series No. 9, Geneva, 1991; HIV–the causative agent of AIDS and related conditions: Second revision of guidelines, Advisory Committee on Dangerous Pathogens, UK, published January 1990; or other appropriate National guidelines). The WHO - UNAIDS and the NIH AIDS Research and Reference Reagent Program accept no liability for any damage, injury or death resulting from the use of these Materials.

7. As a Receiving Party of the Reagent(s) listed above from the WHO - UNAIDS Network for HIV Isolation and Characterization, the Recipient Institution agrees to indemnify and hold harmless the NIH AIDS Research and Reference Reagent Program and WHO - UNAIDS, and their suppliers and contributors of Materials, from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the possession and use of the Reagents or any derivative thereof by the Receiving Party. The individual executing this agreement on behalf of the Recipient Institution warrants that the individual has full authority to do so, and to thereby bind the Recipient Institution.

   If the foregoing conditions are acceptable to you, complete this form and return it to the NIH AIDS Research and Reference Reagent Program, 20301 Century Boulevard, Building 6, Suite 200, Germantown, Maryland 20874.

I CERTIFY THAT I HAVE READ AND ACCEPTED THE CONDITIONS LISTED ABOVE.	
Print Name	Recipient Institution

THIS APPLICATION HAS MY FULL SUPPORT AND APPROVAL.	
Countersignature by Officer of the Institution or Company	
Print Name	Date

The Reagent(s) should be shipped to:	NIH AIDS Reagent Program Account No.:
Full Address:	

FOR SCIENTISTS AT FOR-PROFIT INSTITUTIONS ONLY

WHO - UNAIDS
HIV Vaccine Initiative*

* The WHO-UNAIDS Vaccine Initiative is a joint activity of the World Health Organization (WHO) and the United Nations Programme on HIV/AIDS (UNAIDS).

WHO - UNAIDS Repository: NIH AIDS Research and Reference Reagent Program

Strains/Reagent(s) Requested (please list all reagents):

Justification for Request (give details of research use for which the Strains/Reagents are requested - continue on separate sheet, if necessary):

The above-mentioned Strains/Reagents (hereinafter referred to as "The Material") are provided on the following conditions:

1. The entity requesting and receiving the Materials, hereinafter referred to as "The Receiving Party", agrees that the Material is for research use only and not intended for use in humans. Any use contrary to this statement, as well as use in humans of materials incorporating the Material, are at the sole responsibility of the Receiving Party.

2. The Receiving Party will not permit the Material or any part thereof to come into the possession or control of any other entity or person, except those engaged in research under the supervision of the Receiving Party who have accepted the same obligations in respect of the Material as set forth in this document.

3. The Material may not be transferred or sold to any third party, without the prior authorization in writing from WHO - UNAIDS.

4. This agreement is a material transfer agreement. The supply of the material hereunder does not in any way constitute a license to make, use or sell the Material. The Material is provided to the Receiving Party for the research use described above only. The Receiving Party agrees that the Material itself may not be used for commercial purposes, unless prior written authorization has been granted by WHO - UNAIDS. Such authorization is not, however, required for using the Material for the commercial purpose of making novel non-infectious derivatives, which incorporate the Material. Nothing contained herein will furthermore be construed as restricting the use of such novel non-infectious derivatives for commercial purposes, including, but not limited to, the commercial production of pharmaceutical products. However, in the event that the Material provided hereunder contributes to the development of a product, which is capable of exploitation on an industrial or commercial scale, the Receiving Party shall, account being taken of the relative importance of the contribution of WHO - UNAIDS to the development of such product, use reasonable efforts to ensure that (a) this product is actually developed and made widely available; (b) insofar, as circumstances permit, this product is available, on beneficial terms, to the public health authorities in WHO - UNAIDS Member States, particularly in developing countries.

5. Any publication or presentation of (the results of) the research using the Material, will duly acknowledge WHO - UNAIDS, the Repository and the institutes involved in the provision of the Material to the Repository, including those institutes that were involved in the collection of the relevant blood samples and the relevant virus and strain isolation. The Receiving Party agrees to consult with WHO - UNAIDS in that respect before such publication is published or presentation is made.

6. Any infectious or potentially infectious materials will only be handled in appropriate containment facilities by fully trained and competent staff. (See WHO Biosafety Guidelines: WHO/AIDS Series No 9, Geneva, 1991; HIV-the causative agent of AIDS and related conditions: Second revision of guidelines, Advisory Committee on Dangerous Pathogens, UK, published January 1990; or other appropriate national guidelines.) The Receiving Party will comply with all applicable national legislation when using the Material, including, but not limited to, applicable health safety regulations. WHO - UNAIDS and the Repository accept no liability whatsoever for any damage, injury or death resulting from the use of the Material.

7. The Receiving Party agrees to assume all responsibility for any claims, cost, damages or expenses resulting from or otherwise related to the possession and use of the Material and materials incorporating the Material.

8. On completion of the research using the Material, the Receiving Party will continue to abide by the terms and conditions set forth in this document.

9. The foregoing terms and conditions reflect the terms and conditions pursuant to which WHO - UNAIDS agrees to make the above-mentioned Strains/Reagents available. WHO - UNAIDS expressly reserves the right to make the use of other strains/reagents subject to different terms and conditions than those contained herein.

If the foregoing conditions are acceptable to you, complete this form and return it to the NIH AIDS Research and Reference Reagent Program, 20301 Century Boulevard, Building 6, Suite 200, Germantown, Maryland 20874. Please note, however that signature of this document does not automatically imply that you will receive the Material. Once your request has been approved, arrangements will be made for dispatch of the Material to you (of which arrangements you will be notified). You may wish to take a photocopy of this form for your records.

I CERTIFY THAT I HAVE READ AND ACCEPTED THE CONDITIONS LISTED ABOVE.

I WARRANT THAT I HAVE THE FULL AUTHORITY TO EXECUTE THIS AGREEMENT AND TO THEREBY BIND THE INSTITUTE/OTHER ENTITY RECEIVING THE MATERIAL (I.E. THE RECEIVING PARTY).

Signature	Date
Print Name	Title
Name of Institute/other entity	

THIS APPLICATION HAS MY FULL SUPPORT AND APPROVAL.	
Countersignature by Officer of the Institution or Company	
Print Name	Date

The Reagent(s) should be shipped to:	NIH AIDS Reagent Program Account No.:
Full Address:	

STATEMENT OF INVESTIGATOR FOR IL-2

Hoffman-La Roche Inc.
Nutley, New Jersey 07110

New Drug for Laboratory Study or Animal Tests
Not for Human Use

RECOMBINANT INTERLEUKIN-2

Gentlemen: The following information is submitted to assure you that the shipments to me of the above-designated drug are in conformity with the provisions of Section 312.9 of Title 21 of the Code of Federal Regulations.

I. My Name:

Address:

II. My professional training:

Universities	Degrees	Years

Other professional training (Please attach copies of most recent relevant publications).

III. The facilities to be used in this investigation are (location):

IV. Description of experiments to be carried out: (Describe general nature of experiments and how material will be used):

IV. Dosage form requested: 1 million units/vial, lyophilized from 5 ml.

V. Quantity needed (up to 10 vials per request):

I am regularly engaged in conducting laboratory studies and/or animal tests, and the drug described above will actually be used for laboratory studies and/or animals tests by me under my direct supervision and for no other purposes. The facilities described above are available to me and are adequate for the contemplated investigation. This compound or cells grown in this compound will not be used in humans.

Very truly yours,

Signature:	Date:	DEA Registration Number if required:

THIS AGREEMENT IS FOR NON-PROFIT INSTITUTIONS ONLY.

ADDENDUM TO THE REGISTRATION AGREEMENT FOR THE
NIH AIDS RESEARCH AND REFERENCE REAGENT PROGRAM

APPLICABLE ONLY TO AMD-3100

Non-profit Recipient agrees that the AMD-3100, received from the NIH AIDS Research and Reference Reagent Program will only be used for in vitro and/or studies of HIV replication in animals. Also, note the following release category description for AnorMED, Inc. reagents:

Category E: Recipient must not use or incorporate the reagent for commercial purposes.

AGREED TO BY:

AUTHORIZED PARTY FOR NON-PROFIT RECIPIENT (THE OFFICER SIGNING BELOW MUST BE CAPABLE OF LEGALLY BINDING THE INSTITUTION):
Authorized Signature:
Name/Title (Print):
Date:
Mailing Address:

REQUESTING SCIENTIST:
Signature:
Name/Title (Print):
Date:

APATH

THIS AGREEMENT IS FOR NON-PROFIT INSTITUTIONS ONLY.

ADDENDUM TO THE REGISTRATION AGREEMENT FOR THE
NIH AIDS RESEARCH AND REFERENCE REAGENT PROGRAM

****All for-profit institutions or scientists at non-profit institutions intending Commercial Use (as defined below) must contact Apath directly to sign a licensing agreement for use of these materials****

APPLICABLE ONLY TO REAGENTS DONATED BY APATH, LLC

Non-profit Recipient agrees that before a reagent donated by APATH, LLC to the NIH AIDS Research and Reference Reagent Program is used in a product offered for sale, in a commercial manufacturing process (including quality control and quality assurance procedures), as part of a fee-for service activity, or used in a sponsored research project with a commercial entity ("Commercial Use"), Recipient will contact Apath directly to sign a licensing agreement for Commercial Use of these materials. Note the following release category description for APATH LLC reagents:

Category C: All non-profit Recipients may use the materials for research purposes only. Nonprofit Recipients must sign a licensing agreement with the reagent contributor's Institution for any Commercial Use (as defined above) prior to receiving the reagent. All for-profit institutions must contact the reagent contributor's institution to sign a licensing agreement prior to receiving the reagent.

AGREED TO BY:

AUTHORIZED PARTY FOR NON-PROFIT RECIPIENT (THE OFFICER SIGNING BELOW MUST BE CAPABLE OF LEGALLY BINDING THE INSTITUTION):
Authorized Signature:
Name/Title (Print):
Date:
Mailing Address:

REQUESTING SCIENTIST:
Signature:
Name/Title (Print):
Date:

T-20 ADDENDUM

THIS AGREEMENT IS FOR NON-PROFIT INSTITUTIONS ONLY.

AADDENDUM TO THE REGISTRATION AGREEMENT FOR
THE NIH AIDS RESEARCH AND REFERENCE REAGENT PROGRAM

APPLICABLE TO T-20

Non-profit Recipient agrees that the T-20, donated to the NIH AIDS Research and Reference Reagent Program will only be used for in vitro studies of HIV replication and/or animal studies of HIV replication. Also, note the following release category description for T-20.

Category E: Non-profit Recipient must not use or incorporate the reagent for commercial purposes. Non-profit Recipient will seriously consider Roche's request for an exclusive, nonexclusive or partially exclusive royalty bearing license to make, use and /or sell products embodying inventions as claimed in any filed patent application, subject to the terms of 35 U.S.C. 207, 208, 209 and the implementing regulations.

Non-profit Recipient must provide 2-3 sentences describing the research plan for this reagent:

_____

_____

_____

_____

AGREED TO BY:

AUTHORIZED PARTY FOR NON-PROFIT RECIPIENT (MUST BE CAPABLE OF LEGALLY BINDING THE INSTITUTION):
Authorized Signature:
Name/Title:
Date:
Mailing Address:

REQUESTING SCIENTIST:
Signature:
Name/Title:
Date:

NIH AIDS RESEARCH AND REFERENCE REAGENT PROGRAM
MATERIAL TRANSFER AGREEMENT

Whereas the National Institute of Allergy and Infectious Diseases (NIAID) ("Recipient") and McKesson BioServices Corporation ("Recipient's Contractor") have entered into a U.S. Government contract ("NIAID Contract") to provide biological and chemical materials for the study of HIV and AIDS to the international scientific research community through the NIH AIDS Research and Reference Reagent Program. These materials have been developed by and transferred from various institutions to the Recipient's Contractor for this purpose;

Whereas _____, ("Provider") acting through its investigator _____("Provider Scientist") desires to transfer its materials (identified below as "Research Material") to the Recipient's Contractor for distribution to third parties in accordance with the NIAID Contract to the extent approved by NIAID;

Therefore, Provider and Recipient enter into the following Agreement governing the transfer and use of such materials in accordance with the NIAID Contract.

1. Provider agrees to transfer to Recipient's Contractor the following Research Material (s):

   _____

2. THIS RESEARCH MATERIAL MAY NOT BE USED IN EXPERIMENTS INVOLVING HUMAN SUBJECTS OR FOR ANY CLINICAL DIAGNOSIS WITHOUT RECEIVING PRIOR WRITTEN APPROVAL OF THE PROVIDER AND THE DIRECTOR, DIVISION OF AIDS, NIAID, NIH. Recipient agrees to comply with all Federal rules and regulations, including the Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46, applicable to the use and handling of the Research Material.

3. Are the Research Materials of human origin?
   ___ Yes ___ No
   If you answered Yes above, were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?
   ___ Yes Please provide Assurance Number: _____
   ___ No
   If you answered No above, please explain why in the space below:
   _____
   _____

4. This Research Material will be used by Recipient and Recipient's Contractor solely in connection with its activities under the NIAID Contract under which Recipient's Contractor will maintain the Research Material in its facility and ship it to third parties under the terms of the Registration Form for the NIH AIDS Research and Reference Reagent Program (website: http://www.aidsreagent.org/pdfdocs/register.pdf) and attached hereto at Appendix A, after obtaining approval of NIAID.

5. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Provider reserves the right to distribute the Research Material to others and to

use it for its own purposes. When the NIAID Contract expires, and if it is not renewed, Recipient agrees to instruct its Contractor to dispose of the Research Material as directed by Provider.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

7. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this Agreement. Each party shall be liable for any loss, claim, damage or liability that said party incurs as a result of its activities under this Agreement, except that the parties assume liability only to the extent as provided under applicable laws and regulations.

8. Each reagent made available through the NIH AIDS Research and Reference Reagent Program is assigned to a category related to commercialization rights (see Table 1 below). Therefore, Provider must choose one of the five release categories listed in Table 1.

   To promote commercialization to benefit the public health, Provider is encouraged to select Category A, which sets no restrictions.

Table 1. Commercialization Rights

Release Category	Conditions
A	Reagent may be used for commercial purposes without an agreement with the Provider.
B	Third party agrees to negotiate in good faith to share with the Provider the income arising from commercialization using the reagent.
C	Third party must sign an agreement with the Provider for commercial use prior to receiving the reagent.
D	Third party must select Release Category B or C prior to receiving the reagent.
E	Third party must not use or incorporate the reagent for commercial purposes.

Research Material Designation:	**Release Category:** *(circle only one choice per Research Material)*
_____	**A B C D E**
_____	**A B C D E**
_____	**A B C D E**

9. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

10. This Agreement shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

SIGNATURES BEGIN ON THE NEXT PAGE

NIH AIDS Research and Reference Reagent Program
Material Transfer Agreement Signature Page

AGREED TO BY:

PROVIDER:

<Name> Authorized Signature:

Date: _____ _____
Name/Title

Mailing Address: _____
_____
_____
_____

RECIPIENT:

NIAID Authorized Signature:

Date: _____ _____
Director, Office of Technology Development, NIAID

Address for Notices: Building 31 Room 3B62 http://www.niaid.nih.gov/ttb.htm
31 Center Drive MSC 2137 Telephone: (301) 496-2644
Bethesda MD 20892-2137 Telefax: (301) 402-7123

Acknowledged by:

Provider Scientist

Date: _____ _____
Name/Title

Mailing Address: _____
_____
_____
_____

NIH AIDS Research and Reference Reagent Program
Material Transfer Agreement Signature Page
(Continued)

McKesson BioServices Corporation, a wholly owned subsidiary of McKesson Corporation

Date:_____ _____
General Manager, McKesson BioServices

Mailing Address: NIH AIDS Research and Reference Reagent Program
McKesson BioServices Corporation
20301 Century Blvd
Building 6, Suite 200
Germantown, MD 20874

ATTACHMENT A.4

LIST OF GOVERNMENT- FURNISHED PROPERTY

1. Equipment: Date Acquired

- LKB Gamma Counter, Model 1272-001. 10/88
- LKB Rackbeta Liquid Scintillation Counter, Model 1209-005. 10/88

The above listed Government Furnished Property (GFP) provided to the AIDS Reagent Program is under preventive maintenance contract and is in good working condition.

2. Computer Software:

The NIH ARP catalog of reagents is compiled by the Contractor annually. The Catalog for 2003-2004 was 368 pages. The document was formatted electronically using the following software packages:

- Page Layout and Design: Quark Xpress (version 6.0)
- Text: Microsoft Word 2000 files, saved in Rich Text Format (.RTF) and then imported into Quark.
- Cover: Adobe Illustrator (Version 9), and/or Adobe Photoshop (Version 7)
- Pie Charts: Microsoft Excel 2000. Charts are then converted to bitmap file format (.BMP) and imported into Quark.

All software is PC-compatible with Windows 2000 or XP operating system. The catalog is also provided in PDF format and written to CD. The document can be converted to PDF format via Quark. Hyperlinks/search index are included using Adobe Acrobat Professional (Version 6) and the Infodata Compose plug-in. All catalog files total approximately 22 MB.

The AIDS Reagent Management System (ARMS) was developed using Microsoft Visual Basic. NET for the user interface and Microsoft SQL Server for the database. A major component of the system is the module for tracking individual investigator's reagent acquisitions and receipts. Other modules support production of standard reports, such as receiving and shipping. More specialized reports, including the reagent inventory, investigator affiliations and mailing lists, are also available through this database. ARMS resides on a Dell Power Edge Server. It has separate modules for Accounts, Orders, Receiving, Inventory, Shipping, Reagents, Mailing List and a wide variety of Reports. The main feature of the ARMS is that it is compliant with G(X)P and 21 CFR Part 11 (USFDA Regulations for Electronic Records and Signatures) regulations. This particular software currently occupies 1 GB of space. Since it is a validated system and complies with 21 CFR Part 11, the required storage space expands daily.

3. Paper Files: Thirty, 4-drawer file cabinets of accumulated paperwork.

4. Shipping Materials: Seven, 7-ft shelving units containing packing and shipping materials.

5. Reagents:

The majority of the approximately 300,000 reagents samples, including drugs, are stored in 1.0 or 2.0 ml Nunc tube type vials in various temperature-controlled environments. The reagents are stored under the following conditions:

Storage Temperature (degree Centigrade)		Storage Space (cubic foot)	Number of Samples
24		20	1,500
4-8		40	5,000
-20		1,900	145,000
-40		100	30,000
-80		160	50,000
-135		60	70,000
	Total	**2,280 cu ft**	**301,500**

ATTACHMENT A.5.

DAIDS ENTERPRISE SYTEM SUMMARY

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 Q1 2005.

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 Q1 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 Q3 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 Q4 2005.

The Contractor 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 will 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 the Contractor's 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).

NOTES TO OFFERORS

GENERAL NOTES

1. All offerors must adhere to the following page limitations:

   a. TECHNICAL PROPOSAL: Not-to-exceed 100 pages
   b. STANDARD OPERATING PROCEDURES: Not-to-exceed 100 pages.
   c. BUSINESS PROPOSAL: Not-to-exceed 150 pages.

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

3. RELATED REFERENCE MATERIALS: Offerors interested in responding to this RFP should view the NIH AIDS Reagent Program Home Page at http://www.aidsreagent.org/. They may also request a hardcopy of the 2004-2005 "NIH AIDS Research and Reference Reagent Program Catalog" that includes a current listing of reagents in the AIDS Reagent Program and information on the Reagent Program including forms for registration and requesting for reagents. Requests for a hard copy of Catalog should be addressed to: Liem Nguyen, Contract Specialist, CMP, NIAID, 6700-B Rockledge Drive, Room 3214, Bethesda, MD 20892-7612.

TECHNICAL PROPOSAL NOTES:

1. COMMERCIAL FIRMS – POTENTIAL CONFLICTS: If the offeror is a commercial firm selling or distributing HIV/AIDS and/or emerging infectious disease-related reagents, the offeror should address in detail how potential conflicts of interest will be resolved between their commercial acquisition and distribution of reagents and the acquisition and distribution of similar reagents for the ARP. For example, the offeror must address how they will identify and obtain potentially commercially valuable reagents for ARP distribution and not for their own commercial use.

2. Provide a detailed plan for identifying, prioritizing and acquiring reagents from domestic and international sources. Describe knowledge, experience and qualifications to perform this task. As an indication of knowledge of the field, outline what reagents need to be acquired and how this would be accomplished, including prioritization of the most important acquisitions.

3. Submit documentation that demonstrates: knowledge, experience and competence in quality control analyses of biological and chemical reagents. Provide the following technical proposal information for all proposed subcontractor(s): technical approach, methods, knowledge, experience, personnel qualifications, facilities, resources, etc.

4. Clearly describe your procedures for solicitation, review and selection of subcontractors. Additionally, the relationship between the subcontractor(s) and the Prime Contractor in conducting the Statement of Work must be clearly delineated. How will the offeror manage the subcontract(s)? The Prime Contractor is responsible and accountable for the timeliness and quality of all services and products provided by the subcontractor(s).

5. Describe a plan for how the quality and activity of the acquired reagents will be verified.

6. This contract **will not** support the purchase of general purpose Automated Data Processing (ADP) equipment, hardware and software. The offeror must propose appropriate computer hardware and software to continue this requirement, as well as a plan for maintenance, data input and data back-up and discuss the choice of database and management software it plans to purchase. All software should be Web-based. Assume that the Government will provide the existing ARMS containing information on reagent inventory, including activities of the ARP, along with necessary documentation. (See **ATTACHMENT A.4.** for details on current ARMS.) More specialized reports including the reagent inventory, and investigator affiliations and mailing lists are also available through this database. The ARP Management System and computer files, but not personal computers, will be transferred to the new contractor.

7. Include a documented security and safety plan. Address technical security and personnel conduct standards (appropriate use, enforcement and penalties). Include a Safety and Health Plan with a copy of the offeror's safety and health operating procedures manual. Include evidence of adequate training of personnel to handle:

   a) infectious agents including HIV and opportunistic pathogens associated with HIV infection,
   b) select agents,
   c) radioactive substances, and
   d) accidents, and how to monitor for infection, as well as identify safety standards applicable to particular reagents likely to be acquired.

8. Describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. Personnel assigned to this contract must be bonded and meet all local, State and Federal Regulations and registered, including for access and handling of Category A-C Agents. This includes the following requirements:

   a) USA Patriot Act:
      http://uscis.gov/graphics/lawsregs/patriot.pdf,
   b) Possession, Use and Transfer of Select Agents and Toxins -- current and valid registration for access to and possession of Select Agents:
      http://www.cdc.gov/od/sap/docs/42cfr73.pdf,
      http://www.cdc.gov/od/sap/docs/42cfr73a.pdf,
   c) Agricultural Bioterrorism Protection Act, 7 CFR Part 331 and 9 CFR Part 121:
      http://www.aphis.usda.gov/vs/ncie/pdf/btarule.pdf
      http://www.aphis.usda.gov/vs/ncie/pdf/agri_bioterrorism.pdf

9. Describe an administrative framework indicating clear lines of authority. Provide documentation on the qualification, experience, education, competence, availability and decision-making authority of the Principal Investigator. Resumes and explanation of previous efforts should be provided for Principal Investigator and staff including relevant knowledge, training, experience and specific accomplishments. Resumes should be limited to no more than 2-3 pages each. Documentation should include all previous and current projects of a similar nature, including where applicable, the contract or grant number, sponsoring agency, Project Officer and name and description of the project.

10. TRANSITION PLAN: The Offeror shall include two (2) "transition plans" in the Technical Proposal (and costs in the Business Proposal):

    a) In the event an organization other than the current Contractor is selected, the successful offeror (incoming contractor) will begin to move the ARP Collection (currently located in Germantown, MD), and all Government-furnished property listed under **ATTACHMENT A.4.** to the new site on or about September 2005 (see paragraph 1., of the Statement of Work). Provide a transition plan for the coordination of all relocation tasks between the incumbent and the offeror, and a plan for the conduct of ongoing operation during the transition period. Do not include transition costs with the Technical Proposal

11. STANDARD OPERATING PROCEDURES: Furnish proposed standard operating procedures related to the conduct of this contract . Include samples of inventory control procedures and chain of custody.
    [NOTE: This information is to be provided as as an attachment to the Technical Proposal with a separate page limitation of 100 pages (not included as part of the 100 page limitation for the Technical Proposal). For purposes of transmitting this under the CRON this is required to be submitted as one electronic file. (See Electronic Proposal Instructions in SECTION J of this RFP).]

BUSINESS PROPOSAL – NOTES AND UNIFORM ASSUMPTIONS

1. PURCHASE OF REAGENTS: Based upon experience gained under the current ARP Contract, it is somewhat difficult to predict or identify in advance the types and amounts of reagents and the number of expansions or quality control analyses of reagents that will be required during this contract term. Based upon historical experience, and for the purposes of the offeror in preparing a budget, the Government estimates it will cost $1.6M in Year 1, for reagent purchase, production/expansion and quality control of reagents. It is estimated that this budget item will total $12.3M for seven years, including a 3% yearly inflationary adjustments over the life of the contract. Based on previous experience, 85% of acquired reagents, excluding peptides, are anticipated to be donated by investigators with 65% likely to be expanded with contract funds. All other “acquisition” of reagents was accomplished through purchase and/or subcontract(s).

2. The number of reagent samples stored in the ARP has grown from approximately 127,000 samples in 1997 to over 300,000 samples in 2004. These include over 10,000 unique reagents of which 6,300 are available for public distribution. It is anticipated that new reagents will enter the program on a regular basis, at an estimated rate of 30-50 reagents (500-2000 reagent samples) per month from domestic and international suppliers during each year of this contract. The Offeror should anticipate a 15% increase annually in the number of reagents samples stored in the ARP to an estimated total of 800,000 samples during the term of the contract. Currently, the ARP has an estimated 2,300 cubic feet of low-temperature storage space. Refer to **ATTACHMENT A.4.** to the Work Statement for a list of Government-furnished property, including details on the ARP Management System (ARMS), and details on reagent samples stored at various temperatures.

3. Provide detailed cost proposal information for the subcontractor(s) and final transition.

4. Reagent acquisition is a significant component of this contract. Offerors are encouraged to propose a special reduced indirect rate that applies specifically to reagent purchases.

5. For the purposes of preparing a budget, assume organizing and supporting two one-day workshops annually in the Washington D.C. area with 10 out-of-town invitees.

ADVANCE UNDERSTANDINGS and SPECIAL PROVISIONS (The resultant contract will contain the following.)

1. CONFIDENTIAL TREATMENT OF SENSITIVE INFORMATION -- The Contractor will be required to guarantee strict confidentiality of the information/data that is provided by the Government during the performance of the contract. The Government has determined that some of the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature. Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

2. DATA, DATA RIGHTS, COPYRIGHTS, CONFIDENTIALITY OF INFORMATION -- The information required by the Government will be obtained through the required reports. FAR 52.227-14, Rights in Data, will be incorporated by reference in the solicitation and any resultant contract. Certain data provided to the Contractor shall require confidential treatment. All information regarding the proposed use of reagents by recipients, identity of reagents not published in the Catalog, and identity of identifiers lined to individuals from whom any human derived reagent was obtained is considered proprietary and shall be treated as such. The Contractor is prohibited from releasing, publishing, or disclosing sensitive information to unauthorized personnel, and must protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information: 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records); 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and Public Law 96-511 (Paperwork Reduction Act). The Project Officer will be responsible for determining the level of information availability, and to whom information can be made available.

3. SOFTWARE DEVELOPMENT -- The Contractor must ensure that software applications and standards facilitate the interoperability of data systems and/or the portability of data. All novel software developed under this contract consistent with this aim, is required to be licensed without cost to the Federal Government. The Government may disseminate that technology as it chooses.

4. INTELLECTUAL PROPERTY -- Contractor shall protect reagents and technologies in a timely manner and to ensure their availability to the research community and the public, and through their timely transfer to industry for commercialization. The Contractor agrees that work on this project will not be delayed at any point due to disagreements regarding Intellectual Property either between the Government and the Contractor or between the Contractor and its subcontractor(s).

5. ARTICLE H.__. Possession, Use and Transfer of Select Biological Agents or Toxins

   Work involving select biological agents or toxins shall not be conducted under this contract until the contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents as follows:

   For prime or subcontract awards to **domestic institutions** who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to **foreign institutions** who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC , Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the contractor should provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site.

REPORTING REQUIREMENTS AND DELIVERABLES

RFP NIH-NIAID-DAIDS-05-18

In addition to those reports required by the other terms of this contract, the Contractor will prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract.

Technical Reports

A. **Quarterly Progress Reports:** The Contractor is required to submit two hard copies along with an electronic file of a report of work performed in the previous quarter. The first report will cover the first full three calendar months plus any fractional part of the initial month and will be due on/before _____. Thereafter, reports will be due on or before the 15th of the month following each quarter. A Quarterly Report will not be required for the period when the Annual or Final Report is due. Each Quarterly Report will consist of:

1. A cover page containing:

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

2. Information including a brief summary of the work performed during the reporting period that includes but is not limited to the following:

   (a) An inventory of the quantity and types of each reagent stored as of the last day of each month
   (b) A list of reagents assayed during the month, the types of assays performed, and assay results
   (c) A list of all investigators and sites that have applied for certification as recipients of Category A, B & C, CDC Select Agents (Appendix A to Part 72, CFR 42, http://www.cdc.gov/od/ohs/lrsat/p54605.pdf)
   (d) A summary of all reagents shipped, to include:

      1) Quantity of the reagent
      2) Date of shipment
      3) Date of receipt of shipment
      4) Name and address of the recipient
      5) Problems, if any, associated with shipment.

   (e) A summary of reagents acquired, to include:

      1) Quantity of reagent
      2) Source of reagent
      3) Description of reagent
      4) Quality control information
      5) Restrictions on disposition and use
      6) Size and total cost of reagent
      7) Storage location and how it is stored.

(f) Cumulative list of publications by registrants acknowledging ARP as a source of reagents
(g) Feedback on reagents use
(h) Maintenance problems encountered and corrective action taken
(i) Need for replacement or repair of Government-furnished equipment
(j) Description of current technical or administrative problems encountered and their resolution or proposed corrective action.

B. **Annual Progress Report**

The Annual Report will summarize progress during the entire year and will follow the format for the Quarterly Report. The annual reporting period consists of the each full 12-month period of performance beginning with the effective date of the contract. The report is to be submitted on or before the 15th of the month following each anniversary date of the contract. An Annual Report will not be required for the period when the Final Report is due. The Contactor is required to submit two hard copies along with an electronic file of report.

C. **Draft and Final Transition Plans**

Refer to paragraph 12., of the Statement of Work.

D. **Draft Final Report and Final Report**

The Final Report is to include a summation that documents and summarizes the results of the entire contract for the work performed during the entire period of performance. This report will provide a final inventory and contain a cover page described in A.1 above, and the information required in A.2., above. The Final Report must be in sufficient detail to describe comprehensively the results achieved.

Draft Final Report: The Contractor is required to provide two hard copies along with an electronic copy of the Draft Final Report 45 calendar days prior to the completion date of the contract. One copy is to be provided to the Project Officer and one to the Contracting Officer. The electronic copy should be submitted to both. The Project Officer and Contracting Officer will review the Draft Final Report and provide the Contractor with comments within 30 calendar days after receipt.

Final Report: The Final Report will be corrected by the Contractor, if necessary, and the final version delivered as specified in the above paragraph. The final report is required to be submitted on/before the completion date of the contract.

E. **Summary of Salient Results**

The Contractor is required to submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

F. **Other Deliverables**.

The Contractor, subject to the Contracting Officer's approval, will deliver to the Government or its designee on/before the completion date of the Contract, the following items:

1. Preserved reagent samples and Government owned equipment
2. ARP Management System and documentation of computer systems and files, including source codes, instruction manuals and data collected

3. Computerized listing of accurate and updated information on reagent inventory, including activities of the ARP, data files, databases, original data, and any necessary information related to the ARP
4. Labeled and inventoried paper files

G. Copies of the technical reports are to be submitted as follows:

Item	Deliverable	No. of Copies	Delivery Date
1.	Quarterly Progress Report	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due on/before the 15th calendar day after completion of each quarter. Not due when Annual or Final Reports are due.
2.	Annual Report	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due on/before the 15th of the month following each anniversary date of the contract. Not due when Final Report is due.
3.	Draft Transition Plan	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due 24 months after the effective date of the contract.
4.	Final Transition Plan	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due 12 months prior to the completion date of the contract.
5.	Draft Final Report	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due 45 calendar days before the completion date of the contract.
6.	Final Report	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due on/before the completion date of the contract.
7.	Summary of Salient Results	1 Original – C.O. 1 Copy – P.O. 1 Elec. File – PO & CO	Due with the Final Report.

H. Addressees

Project Officer
DAIDS, NIAID, NIH
6700-B Rockledge Drive
Bethesda, MD 20892

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

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

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

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

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

ARTICLE I.1. GENERAL CLAUSES

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

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

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

ARTICLE I.1 of this SECTION is hereby modified as follows:

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 therefore. [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.]

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

In addition to the applicable Additional Contract Clauses listed at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf , the following items are relevant 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 as follows:

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

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

ITEM 51: The following Alternate is applicable to this solicitation:

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

ITEM 52: FAR Clause **52.227-16, Additional Data Requirements** (JUNE 1987)

ITEM 60: FAR Clause **52.237-3, Continuity of Services** (JANUARY 1991), is applicable to this solicitation.

ITEM 64: FAR Clause **52.242-12, Report of Shipment (REPSHIP)** (JUNE 2003), is applicable to this solicitation.

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

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

No additional or supplemental Additional FAR Contract Clauses Included in Full Text are applicable. See **I.4. Additional FAR Contract Clauses Included in Full Text** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional FAR Contract Clauses Included in Full Text.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

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

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

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

PROPOSAL INTENT RESPONSE SHEET - SUBMIT ON/BEFORE February 7, 2005 (Attached to this listing)

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

RFP FORMS AND ATTACHMENTS:

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

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

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

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **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**
- **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 *[if applicable]***
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule IIA – Property Acquired Under Predecessor Contract N01-AI-85332**
- **Disclosure of Lobbying Activities, OMB Form LLL**
- **Commitment to Protect Non-Public Information – Contractor Agreement**
- **Roster of Employees Requiring Suitability Investigation**

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.

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DAIDS-05-18
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Liem T. Nguyen Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Liem T Nguyen Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

C. NUMBER OF COPIES:

TECHNICAL PROPOSAL PAGE LIMITS INCLUDE: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc..

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

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 PORTION OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY WILL BE 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.

The number of copies required of each part of your proposal are as specified below.

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
Standard Operating Procedures (part of Technical Proposal submission)	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies	Limited to not-to-exceed 100 pages	To be included in the 5 megabyte limit for the entire Technical Proposal submission.
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 each contain electronic versions of all proposal information (both technical and business – clearly named). If information appended to the paper version is not available electronically, the CD shall contain a file listing all documents that are submitted in paper format only. **The offeror shall include certification that the documents provided electronically match the paper version of those same documents.**		2 Compact Discs (CDs): Each containing the Technical Proposal and SOPs: 1 Compact Disc (CD): Business Proposal only	

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 this attachment and must be received on/before the closing date and time.

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

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Documents must be converted to a .pdf searchable format.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT RESPONSE SHEET":

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

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

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

LOG-IN / TRANSMISSION INSTRUCTIONS:

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

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

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

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

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-05-18
RFP Title: AIDS RESEARCH AND REFERENCE REAGENT PROGRAM

Please review the attached Request for Proposal. Furnish the information requested below and return this page by February 7, 2005. 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: Liem T. Nguyen
RFP-NIH-NIAID-DAIDS-05-18
FAX# (301) 480-4675
Email : ln18x@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.

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: NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SDB CONCERNS. 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 10 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 September 26, 2005.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract with a period of performance of seven 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 9 full time equivalents (FTEs) per year. 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 28: Possession, Use and Transfer of Select Biological Agents or Toxins, is applicable to this solicitation.

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

ITEM 32: Specific Copyright Provisions Applicable to Software Development and/or Enhancements, is applicable to this solicitation and the following information is provided to assist in proposal preparation:

Under the provisions of the Rights in Data General Clause (52.227-14), offerors will be required to seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. **This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract. The scope of the Government's interest in the copyright will be determined during negotiations.**

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, is 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 contracts completed during the past five years and the last three 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 55: **Information Technology Systems Security,** is applicable to this solicitation.

IMPORTANT NOTE TO OFFERORS: This information should be addressed in a separate section of the Technical Proposal entitled, "Information Technology Systems Security."

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.
[ ] The following format shall be used in lieu of the one specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf :*

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 65: **Royalties,** is applicable to this solicitation.

ITEM 66: **Incremental Funding**, is applicable to this solicitation.

ITEM 68: **Certification of Visas for Non-U.S. Citizens**, is applicable to this solicitation.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated Offeror. In any event, the Government reserves the right to make an award(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. TECHNICAL EVALUATION CRITERIA

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

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

	CRITERIA	**WEIGHT**
A.	**TECHNICAL APPROACH**	**50 POINTS**

The technical adequacy, feasibility, safety and effectiveness of the detailed and specific plans demonstrating knowledge, organizational experience and competence, ability to award and manage subcontracts, standard operating procedures, and quality control measures proposed for operation of an AIDS Reagent Program (ARP), including:

(1) Reagent Management, Production and Quality Control (25 points)

(a) Identification, prioritization, and acquisition of reagents for HIV/AIDS and associated opportunistic agents from domestic and international sources; overall management plan of the offeror and all subcontractors including communication, reagent production and quality control oversight and reporting; production/expansion of reagents; evaluation of the quality and activity of the reagents; demonstrated knowledge, experience and competence of the Contractor and any and all subcontractors for performance of production and quality control analyses of biological and chemical reagents, including GMP-produced materials.

(b) For Select Agents, information showing that the foreign institution's process is equivalent to that described in 42 CFR Part 73 for U.S. institutions and will be used for all select agent work conducted with NIH funds.

(c) If a process similar to the one in 42 CFR 73 is not in place, information about safety, security, and training, and procedures for ensuring that only approved and appropriate persons have access to select agents as well as applicable laws, regulations and policies.

(d) Certification by the institutional or responsible official that the institution has facilities meeting requirements to work safely with select agent or agents, only authorized personnel have access to select agents, and the institution keeps records of select agents transferred to and from its facilities.

(2) ARP Contract Management (25 points)

(a) Quality of the Standard Operating Procedures submitted for the operation of the ARP; ability to manage a contract in accordance with the proposed schedule and budget; ability to award and manage sub-contracts; reporting and communication of schedule and budget status to the government on a regular basis; coordination of ARP operation of through interaction with the HIV/AIDS research community in academia, government, biotechnology and pharmaceutical companies, technology transfer officials (worldwide), and the Division of AIDS, including the sponsorship of workshops and awareness-promoting activities; a plan for providing editorial and publishing services for the catalog of reagents; an operations plan for resolving potential conflicts of interest if a commercial organization is acquiring potentially valuable reagents for the Offeror's commercial use rather than for ARP; effecting a smooth transition between current Contractor and successor Contractor, including assistance to ensure a safe and efficient move of the ARP; and the coordination of an orderly transition.

(b) Inventory Control and Distribution

Maintaining and updating secure internal information database systems. Tracking all ARP activity-related information via the Internet including reagent inventory, shipment, receipt, assay information and quality control. Documentation of the Offeror’s ability to manage and operate a GMP facility that receives, stores and ships biohazardous and infectious materials.

B. KNOWLEDGE AND TECHNICAL CAPABILITIES OF PERSONNEL 30 POINTS

(1) Principal Investigator (15 Points)

Documented training, experience and availability of a Principal Investigator. The technical and administrative competence to operate the ARP, or a Project of comparable size and complexity. The proposed Principal Investigator should have a Ph.D. or its equivalence in microbiology; demonstrated knowledge and research experience in HIV/AIDS in order to identify and prioritize reagents for HIV/AIDS and infectious diseases community; experience to award and effectively manage subcontracts; experience and expertise in working with Select Agents and GMP Biosafety Level (BSL)-2/3 containment; and ability to provide technical assistance and oversight, including specific training and guidance in the safe and proper handling of hazardous, infectious, and pathogenic agents.

(2) Training and Experience of Other Staff (15 Points)

Documented training, experience and availability of other professional and support staff necessary to successfully carry out the proposed work scope of the ARP, including experience and expertise with HIV/AIDS reagents, experience to award and effectively manage subcontracts, demonstrated editorial and scientific writing expertise (preferably for infectious diseases) sufficient to prepare the ARP catalog and promotional literature; documented laboratory competence and familiarity with safety regulations; and Internet site maintenance experience. Support personnel shall include those knowledgeable of and in compliance with current local, state and Federal safety guidelines, and policies and regulations including IATA and DOT training requirements for shipping and receiving infectious and hazardous substances.

C. FACILITIES AND MANAGEMENT 20 POINTS

Documented availability of adequate facilities, equipment and organizational resources necessary for safe and secure operation and maintenance of the ARP; facilities to ship, receive, store and maintain the activity and viability of reagents. As evidence of adequate facilities, equipment, organizational structure and resources, the Offeror should provide the following:

(a) a detailed floor plan of the proposed facility indicating location of equipment and resources

(b) information regarding ownership/lease of the facility, demonstrating the availability for the duration of the proposed contract including availability upon start of contract

(c) a detailed description of equipment proposed for the project and its availability (i.e., percentage of time equipment will be dedicated to the project, or in the case of freezers the percentage of storage space currently available for the project)

(d) a logistics plan for storing, packaging and shipping reagents nationally and internationally, including a notification mechanism for reagent receipt date and condition of reagent upon receipt; a logistics plan for receiving, processing and storing incoming reagent shipments

(e) a plan for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents

(f) information concerning the adequacy of all physical and electronic security systems to prevent unauthorized entry into the facility, and adequate security systems to prevent unauthorized access of the ARP computer databases and other computer-associated systems, programs and files; alarm systems for emergency and equipment malfunction situations, etc.

(g) evidence of the possession of any current special licenses or local permits that may be needed (e.g. infectious agents, radioactive incense, controlled substances)

(h) an organizational chart delineating lines of authority, and the management scheme for specific tasks, reporting responsibilities, coordination with DAIDS, and quality control procedures

(i) organizational experience

TOTAL: 100 POINTS

3. PAST PERFORMANCE FACTOR

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

The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the Offeror concerning problems previously encountered during the performance of identified contract(s) and the corrective action taken.

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

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

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

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offeror's performance. The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

Extent of Small Disadvantaged Business (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 participants for the work that it intends to perform.

Offerors will be evaluated on the following sub-factors:

(a) Extent to which SDB participants are specifically identified
(b) Complexity and variety of the work SDB participants are to perform
(c) Extent of participation of SDB participants in terms of the value of the total acquisition.

5. **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.