

Sources Sought Notice No.: SS-ETSB-91014-56

Project Title: Support for Research on Retroviral Pathogenesis, Treatment and Prevention

This is a Small Business Sources Sought notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business concern; (2) whether they are small business; HUBZone small business; service-disabled, veteran-owned small business; 8(a) small business; veteran-owned small business; woman-owned small business; or small disadvantage business; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.

The NAICS code for this project is 541380.

The small business size standard is \$12 million in annual receipts.

Background

A contract previously supported research of the Section on Animal Models and Retroviral Vaccines (AMRV) and the Section on Immune Biology of Retroviral Infection (IBRI) within the Basic Research Laboratory, NCI. When the Vaccine Branch (VB) was created within the Cancer for Center Research (CCR), the contract was available for use not only by the AMRV and the IBRI, but also the Human Retrovirus Section, the Human Retrovirus Pathogenesis Section, and the Molecular Immunogenetic and Vaccine Research Section. A key area of research in the VB involves retroviruses, particularly HIV, the causative agent of AIDS, and SIV, the related monkey virus which provides a model for detailed experimental investigations. Other viruses are studied as well, including HTLV-1/2, and viruses used as vaccine vectors. Vaccine approaches are a major area of research, however studies on viral pathogenesis and treatment are also ongoing. Previous contracts have provided critical support to these research endeavors. Contract activities have included provisions of retroviruses, purified retroviral and cellular proteins, polyclonal and monoclonal antibodies and cell culture support; and performance of assays to assess the immunological status of research subjects and the virological status of cells and tissues in vivo and in vitro.

This work is currently being conducted under contract N02-RC-47703 held by Advanced BioScience Laboratories, Inc.

Definitions

HIV	Human Immunodeficiency Virus
SIV	Simian Immunodeficiency Virus
HTLV-1/2	Human T-cell leukemia virus type I and II
DNA	Deoxyribonucleic acid
PCR	Polymerase Chain Reaction

Purpose and Objectives

The purpose of this project is to provide support for research on retroviral (specifically HIV and HTLV) pathogenesis and vaccine development in the areas of virology, immunology, protein biochemistry, and molecular biology. Virologic support is needed for isolation and characterization of retroviruses, development of viral stocks for in vitro assays, and in support of studies on viral variation and evolution and pathogenesis studies. Immunologic support is needed for evaluation of immunity elicited by candidate vaccines, seroprevalence studies of retroviruses as well as vaccine vectors, and elucidation of correlates of protective efficacy. The protein biochemistry component is critical as it is needed to provide purified proteins and peptides for use as immunogens and as reagents for evaluation of candidate vaccines. Molecular biologic support is essential for quantitative assessment of viral loads in vaccine and pathogenesis studies and for provision of nucleic acid reagents.

Project requirements

Major tasks required of the Contractor include the following:

- 1) Prepare and provide large bulk amount of B or T cell lines from blood of non-human primates or humans
- 2) Conduct in vitro culture and detection of retroviruses from peripheral blood and/or tissues of humans or animals, the latter including rodents, leporidae and non-human primates.
- 3) Provide tittered stocks of field isolates for in vitro use from virus-infected humans and non-human primates at low passage number on human or non-human primate Peripheral Blood Mononuclear Cell (PBMC).
- 4) Provide purified and tittered stocks of attenuated and vaccinia virus recombinants as requested by the Project Officer. The initial viral inocula shall be provided by the Government.
- 5) Conduct in vitro assays to assess the serologic status of human or animal sample donors, to evaluate the prevalence of virus present within its host population, and to evaluate secretion of cytokines.
- 6) Purify lymphocytes from blood, lymph nodes or other tissues from animal or humans and provide fresh and viable to the government.
- 7) Provide purified, biochemically characterized and biologically active native viral or cellular proteins from viruses, infected cells, or conditioned media and from bacterial or mammalian expression systems.
- 8) Design codon-optimized genes encoding cellular or viral proteins for eukaryotic or prokaryotic expression.
- 9) Provide overlapping peptides representing proteins from the HIV, SIV, HTLV-1/2, or adenovirus genomes.
- 10) Provide pre-clinical grade plasmid DNA containing minimal levels of endotoxin and encoding HIV and SIV genes for vaccine studies.
- 11) Purify and quantitate mRNA in plasma or tissue samples of animals or humans by real time PCR.
- 12) Conduct assays to quantitate proviral DNA load by real time PCR for SIV or HTLV-1/2 from cells of non-human primates.

- 13) Provide characterized monoclonal and polyclonal antibodies to proteins of interest for use in affinity purifications, immunologic characterizations, and for VB use.
- 14) Provide long-term storage for viable cell lines, tittered field isolates, viral challenge stocks and viable cell specimens from inoculated and immunized animals.

Tissues and blood cells required in the performance of the above tasks will be provided by the Government.

As part of the work under this potential contract semiannual and final technical report are expected.

Other important considerations

All biological materials delivered will need to be packaged in appropriate containers and delivered according to Department of Transportation regulations.

This work requires the Contractor to have or establish biocontainment (BSL2 with BSL3 capability) in order to conduct work with human retroviruses and non-human primate retroviruses (HIV, SIV, SHIV, HTLV -1/2) adenovirus, and poxviruses.

This work also requires the delivery of fresh, viable cells and biologically active purified proteins to Bethesda, Maryland within one hour after preparation and the pickup of fresh, viable cells and tissues from primates maintained by the Government in Rockville, Maryland within one hour of notice of harvest by the Government.

Anticipated period of performance

The anticipated period of performance for this requirement is one year, with four one-year options.

Capability statement/information sought.

Interested qualified small business organizations should submit a tailored capability statement for this requirement, not to exceed 20 single-sided pages (including all attachments, resumes, charts, etc.) presented in single-space and using a 12-point font size minimum, that clearly details the ability to perform the aspects of the notice described above. Statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement, as well as the eligible small business concern's name, point of contact, address and DUNS number.

Information submission instructions

All capability Statements sent in response to this SOURCES SOUGHT notice must be submitted electronically (via email) to Juana A. Diaz, Contract Specialist, at diazj@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF), by February 2, 2009, 3:30PM, EST. All responses must be received by the specified due date and time in order to be considered.

Disclaimer and Important Notes

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. Respondents will be added to the prospective offerors list for any subsequent solicitation. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality

No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary information in any resultant solicitation(s).